IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MADLYNE BOBO, EMA HERNANDEZ, RONALD HUGHES, DAWN CARPENTER, RICHARD CARPENTER, ODESSA CHARBONEAU, RONNINE HERNANDEZ, CYNTHIA BOYD, GEORGIA BENJAMIN, SHANIA CLARKE, CHRISTY TURNER, MISCHELL HALL, CASAUNDRA WIGGINS, ELISHA WILBORN, STEPHANIE LOUCKS, DUSTIN LOUCKS, DYANNA LUCAS, MICHELLE VAUGHN, EUGENA DAVIS, RECO DAVIS, SHAREKA CARLEY, WEINA SAMPSON, JACKLYN GERLACH, ELLEN BALL, DOMONIQUE DANTZLER, TIFFANY MESSENGER, ANDREA WILKSINSON, MONIQUE QUEVEDO,SHANNON GOLDEN, MICHAEL GOLDEN, JANE CUEVAS, DARYALE FRANKLIN, JARMAIN FRANKLIN, ROSENA PATTERSON, DARLENE VERNO, JACQUELINE GOSE, MICHELE BURKE, DANIEL BURKE, KEANUA FELTON, AMANDA BURNS, JESSICA HERNANDEZ, CRYSTAL THORNTON, GREG THORNTON, SHELLY HOWARD, SABRINA COLDING, VANESSA OATES, DAVID OATES, MAUREEN BURTON, CATHERINE COOPER, MIKESHA BARNETT, TITIANA BROOKS, CARMINA REYES, JENNIFER WISE, MARC WISE, DENEACE WALKER, THERESA CHANDLER, MARCUS CHANDLER, KATIE FRYE, CHIMENE KIRKHAM, HAROLD KIRKHAM,

Plaintiffs,

vs.

NO.: _____

JURY TRIAL DEMANDED

BAYER HEALTHCARE
PHARMACEUTICALS, INC.,

Defendants.

COMPLAINT FOR DAMAGES

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NOW COME Plaintiffs, MADELYNE BOBO, EMA HERNANDEZ, RONALD HUGHES, DAWN CARPENTER, RICHARD CARPENTER, ODESSA CHARBONEAU, RONNIE HERNANDEZ, CYNTHIA BOYD, GEORGIA BENJAMIN, SHANIA CLARKE, CHRISTY TURNER, MISCHELL HALL, CASAUNDRA WIGGINS, ELISHA WILBORN, STEPHANIE LOUCKS, DUSTIN LOUCKS, DYANNA LUCAS, MICHELLE VAUGHN, EUGENE DAVIS, RECO DAVIS, SHAREKA CARLEY, WEINA SAMPSON, JACKLYN GERLACH, ELLEN BALL, DOMONIQUE DANTZLER, TIFFANY MESSENGER, ANDREA WILKSINSON, MONIQUE QUEVEDO, SHANNON GOLDEN, MICHAEL GOLDEN, JANE CUEVAS, DARYALE FRANKLIN, JARMAIN FRANKLIN, ROSENA PATTERSON, DARLENE VERNO, JACQUELINE GOSE, MICHELE BURKE, DANIEL BURKE, KEANUA FELTON, AMANDA BURNS, JESSICA HERNANDEZ, CRYSTAL THORNTON, GREG THORNTON, SHELLY HOWARD, SABRINA COLDING, VANESSA OATES, DAVID OATES, MAUREEN BURTON, CATHERINE COOPER, MIKESHA BARNETT, TITANA BROOKS, CARMINA REYES, JENNIFER WISE, MARC WISE, DENEACE WALKER, THERESA CHANDLER, MARCUS CHANDLER, KATIE FRYE, CHIMENE KIRKHAM, HAROLD KIRKHAM who, in filing this Complaint, seek judgment against Defendants BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER ESSURE, INC.; and BAYER HEALTHCARE, LLC (hereinafter collectively referred to as "Defendants") for the personal injuries they sustained as a result of being prescribed, receiving, and subsequently using the defective and unreasonably dangerous permanent birth control device Essure®. At all times relevant hereto, Essure® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold by Defendants or Conceptus, Inc., which was acquired by Defendant on or about April 28, 2013.

I

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Madelyne Bobo is a citizen of Florence, Arizona.

2. Plaintiff Ema Hernandez is a citizen of Gardena, California.

3. Plaintiff Ronald Hughes is a citizen of Gardena, California.

4. Plaintiff Dawn Carpenter is a citizen of San Bernardino, California.

5. Plaintiff Richard Carpenter is a citizen of San Bernardino, California.

6. Plaintiff Odessa Charboneau is a citizen of Biggs, California.

7. Plaintiff Ronnine Hernandez is a citizen of Elk Grove, California.

8. Plaintiff Cynthia Boyd is a citizen of Santa Monica, California.

9. Plaintiff Georgia Benjamin is a citizen of Clermont, Florida.

10. Plaintiff Shania Clarke is a citizen of Deland, Florida.

11. Plaintiff Christy Turner is a citizen of River Beach, Florida.

12. Plaintiff Mischell Hall is a citizen of Jacksonville, Florida.

13. Plaintiff Casaundra Wiggins is a citizen of Douglasville, Georgia.

14. Plaintiff Elisha Wilborn is a citizen of Ellenwood, Georgia.

15. Plaintiff Stephanie Loucks is a citizen of Steeleville, Illinois.

16. Plaintiff Dustin Loucks is a citizen of Steeleville, Illinois.

17. Plaintiff Dyanna Lucas is a citizen of Mattoon, Illinois.

18. Plaintiff Michelle is a citizen of Vaughn Aurora, Illinois

19. Plaintiff Eugena Davis is a citizen of Louisville, Kentucky.

20. Plaintiff Reco Davis is a citizen of Louisville, Kentucky.

21. Plaintiff Shareka Carley is a citizen of Shreveport, Louisiana.

22. Plaintiff Weina Sampson is a citizen of Holden, Massachusetts.

23. Plaintiff Jacklyn Gerlach is a citizen of Flint, Michigan.

24. Plaintiff Ellen Ball is a citizen of Taylor, Michigan.

25. Plaintiff Domonique Dantzler is a citizen of Detroit, Michigan.

26. Plaintiff Tiffany Messenger is a citizen of Clarksdale, Mississippi.

27. Plaintiff Andrea Wilkinson is a citizen of Jackson, Missouri.

28. Plaintiff Monique Quevedo is a citizen of Albuquerque, New Mexico.

29. Plaintiff Shannon Golden is a citizen of Ridge, New York.

30. Plaintiff Michael Golden is a citizen of Ridge, New York.

31. Plaintiff Jane Cuevas is a citizen of New York, New York.

32. Plaintiff Daryale Franklin is a citzen of Pineville, North Carolina.

33. Plaintiff Jarmain Franklin is a citizen of Pineville, North Carolina.

34. Plaintiff Rosena Patterson is a citizen of Matthews, North Carolina.

35. Plaintiff Darlene Verno is a citizen of Humbard, Ohio.

36. Plaintiff Jacqueline Gose is a citizen of Akron, Ohio.

37. Plaintiff Michael Burke is a citizen of Cincinnati, Ohio.

38. Plaintiff Daniel Burke is a citizen of Cincinnati, Ohio.

39. Plaintiff Keanua Felton is a citizen of Dayton, Ohio.

40. Plaintiff Amanda Burns is a citizen of Warminster, Pennsylvania.

41. Plaintiff Jessica Hernandez is a citizen of Exton, Pennsylvania.

42. Plaintiff Crystal Thorton is a citizen of Connellsville, Pennsylvania.

43. Plaintiff Greg Thornton is a citizen of Connellsville, Pennsylvania.

44. Plaintiff Shelly Howard is a citizen of Verona, Pennsylvania.

45. Plaintiff Sabrina Colding is a citizen of Philadelphia, Pennsylvania.

46. Plaintiff Vanessa Oates is a citizen of Philadelphia, Pennsylvania.

47. Plaintiff David Oates is a citizen of Philadelphia, Pennsylvania.

48. Plaintiff Maureen Burton is a citizen of Norristown, Pennsylvania.

49. Plaintiff Catherine Cooper is a citizen of Collierville, Tennessee

50. Plaintiff Mikesha Barnett is a citizen of Carrolton, Texas.

51. Plaintiff Titiana Brooks is a citizen of Fort Worth, Texas.

52. Plaintiff Carmina Reyes is a citizen of San Antonio, Texas.

53. Plaintiff Jennifer Wise is a citizen of Rutland, Vermont.

54. Plaintiff Marc Wise is a citizen of Rutland, Vermont.

55. Plaintiff Deneace Walker is a citizen of Newport News, Virginia.

56. Plaintiff Theresa Chandler is a citizen of Dumfries, Virginia

57. Plaintiff Marcus Chander is a citizen of Dumfries, Virginia.

58. Plaintiff Katie Frye is a citizen of Edmonds, Washington.

59. Plaintiff Chimene Kirkham is a citizen of Tenino, Washington.

60. Plaintiff Harold Kirkham is a citizen of Tenino, Washington.

61. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC., is a for-profit corporation incorporated in the state of Delaware. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.'s headquarters are located at 100 Bayer Boulevard, Whippany, New Jersey. Defendant is authorized to and does business throughout the Commonwealth of Pennsylvania.

62. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because complete diversity in citizenship exists between the Plaintiffs and the

Defendant, and the amount in controversy exceeds seventy-five thousand dollars ($75,000) exclusive of interest and costs.

63. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) and (3) because a substantial part of the events or omissions giving rise to the claim occurred in this district, and the Defendant regularly transact substantial business in this district and are subject to personal jurisdiction in this district. Additionally, the Defendant advertised in this district and have received substantial revenue and profits from their sales of Essure® devices in this district; therefore, a substantial part of the events and/or omissions giving rise to the claims occurred, in part, within this district.

64. This Court has personal jurisdiction over the Defendant because they have conducted substantial business in this judicial district and, intentionally and purposefully, placed the Essure® devices into the stream of commerce within Pennsylvania and throughout the United States.

II

INTRODUCTION

65. This Complaint is brought by Plaintiffs who were implanted with a female birth control device known as "Essure." In short, the device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage. However, in reality, the device migrates from the tubes, perforates organs, breaks into pieces and/or corrodes, wreaking havoc on the female body.

66. As a result of (1) Defendant's negligence described *infra* and (2) Plaintiffs' reliance on Defendant's warranties and representations, Defendant's Essure devices migrated, fractured, punctured internal organs, and/or caused other serious injuries.

67. Essure had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, Essure became "adulterated" and "misbranded"due to (1) Defendant's failure to conform to the FDA requirements prescribed in the CPMA and (2) violations of federal statutes and regulations noted *infra.*

68. Pursuant to Defendant's CPMA (which reads: "Failure to comply with conditions of approval invalidates this approval order"), the C.F.R., and Federal Food, Drug and Cosmetic Act ("FDCA"), the product is "adulterated" and "misbranded" and, thus, could not have been marketed or sold to Plaintiffs.

69. Specifically, Essure was adulterated and misbranded as the Defendant (1) failed to meet regular reporting requirements; (2) failed to report known hazards to the FDA; and (3) failed to comply with federal laws regarding marketing and distribution as specifically described *infra*.

70. The fact that the Defendant failed to comply with these conditions is not a mere allegation made by Plaintiffs. These failures to comply with both the CPMA and federal regulations are memorialized in several FDA findings, including Notices of Violations and Form 483s issued by the FDA.

71. As discussed in greater detail *infra*, the Defendant was cited by the FDA and the Department of Health for:

a. failing to report and actively concealing eight (8) perforations which occurred as a result of Essure;

b. erroneously using non-conforming material in the manufacturing of Essure;

c. failing to use pre-sterile and post-sterile cages;

d. manufacturing Essure at an unlicensed facility; and

e. manufacturing Essure for three (3) years without a license to do so.

72. Defendant was also found, by the FDA, to be:

a. Not reporting complaints in which their product migrated;

b. Not reporting to the FDA incidents of bowel perforation, Essure coils breaking into pieces and migrating out of the fallopian tubes.

c. Only disclosing 22 perforations while having knowledge of 144 perforations;

d. Not considering these complaints in their risk analysis for the design of Essure;

e. Failing to have a complete risk analysis for Essure;

f. Failing to analyze or identify existing and potential causes of non-confirming product and other quality problems;

g. Failing to track the non-conforming product;

h. Failing to follow procedures used to control products which did not conform to specifications;

i. Failing to have complete Design Failure Analysis;

j. Failing to document CAPA activities for a supplier corrective action;

k. Failing to disclose 16,047 complaints to the FDA as Medical Device Reports ("MDR"); and

l. Failing to provide the FDA with timely post-approval reports for its six months, one year, eighteen months, and two years report schedules.

73. Most egregiously, on May 30, 2013, the FDA uncovered an internal excel spreadsheet with 16,047 entries of complaints which were not properly reported to the FDA. Here, Defendant did not disclose to the FDA complaints where its product migrated outside of the fallopian tube. Defendant's excuse was that those complaints were not reported because the patients were "not at last contact experiencing pain….and were mere trivial damage that does not rise to the level of a serious injury." The FDA again warned Defendant for violations of the FDCA.

74. As a result, the "adulterated" and "misbranded" product, Essure, which was implanted in Plaintiffs, should never have been marketed or sold to Plaintiffs pursuant to federal law.

75. Lastly, Defendant concealed and altered the medical records of its own clinical trial participants to reflect favorable data. Specifically, Defendant altered medical records to

reflect less pain than what was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process. Subsequently, Defendant failed to disclose this and concealed it from Plaintiffs and their implanting physicians.

76. Plaintiffs' causes of action are all based on deviations from the requirements in the CPMA and/or violations of federal statutes and regulations.

77. Plaintiffs' causes of action are also based entirely on the express warranties, misrepresentations, and Defendant's deceptive conduct, which were relied upon by Plaintiffs prior to having the device implanted. Under Pennsylvania law, Plaintiffs' claims for breach of express warranties are not preempted by the Medical Device Act ("MDA").

78. In addition, Defendant failed to comply with the following express conditions and federal regulations:

a. "Within 10 days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

b. "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

c. Report Due Dates – six months, one year, eighteen months, and two-year reports.

d. A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

e. Effectiveness of Essure is established by annually reporting on the 745 women who participated in the clinical tests.

f. Successful bilateral placement of Essure is documented for newly trained physicians.

g. Warranties are truthful, accurate, and not misleading.

h. Warranties are consistent with applicable federal and state law.

79. These violations rendered the product "adulterated" and "misbranded" – precluding Defendant from marketing or selling Essure and, more importantly, endangered the lives of Plaintiffs and hundreds of thousands of women.

80. Defendant actively concealed these violations and never advised Plaintiffs of the same. Had Plaintiffs known that Defendant was concealing adverse reactions, not using conforming material approved by the FDA (and failing to track the nonconforming material), not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license, they never would have had Essure implanted.

III

DESCRIPTION OF ESSURE AND HOW IT WORKS

81. Essure is a permanent form of female birth control (female sterilization). The device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage.

82. Essure consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use.

83. The micro-inserts are comprised of two (2) metal coils which are placed in a woman's fallopian tubes via Defendant's disposable delivery system and under hysteroscopic guidance (camera).

84. The hysteroscopic equipment needed to place Essure was manufactured by a third party, is not a part of Defendant's CPMA, and is not a part of Essure. However, because Plaintiffs' implanting physicians did not have such equipment, Defendants provided it so that it could sell Essure.

85. The coils are comprised of nickel, steel, nitinol, and PET fibers. In other words, the coils are metal-on-metal.

86. Defendant's disposable delivery system consists of a single handle which contains a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians are

allowed to visualize this complicated process through the hysteroscopic equipment provided by Defendant.

87. After placement of the coils in the fallopian tubes by Defendant's disposable delivery system, the micro-inserts expand upon release and are intended to anchor into the fallopian tubes. The PET fibers in the coil allegedly elicit tissue growth blocking off the fallopian tubes.

88. The coils are supposed to remain securely in place in the fallopian tubes for the life of the consumer and not migrate, break, or corrode.

89. Three months after implant, patients are to receive a "Confirmation" test to determine if the micro-inserts are in the correct location and that the tissue has created a complete occlusion. This is known as a hysterosalpingogram ("HSG Test" or "Confirmation Test").

90. Regardless of the Confirmation Test, Defendant warrants that Essure allows for visual confirmation of each inserts proper placement during the procedure.

91. Essure was designed, manufactured, and marketed to be used by the average gynecologist as a "quick and easy" and "non-surgical" outpatient procedure to be done without anesthesia.

IV

EVOLUTION OF ESSURE

92. Essure was first designed and manufactured by Conceptus, Inc. ("Conceptus").

93. Conceptus and Defendant merged on or about April 28, 2013.

94. For purposes of this lawsuit, Conceptus and Defendant is one in the same.

95. Essure, a Class III medical device, is now manufactured, sold, distributed, marketed, and promoted by Defendant.

96. Defendant trained physicians, including Plaintiffs' implanting physicians, on how to implant Essure and use hysteroscopic equipment.

97. Prior to the merger between Conceptus and the Bayer defendant, Conceptus obtained CPMA for Essure.

98. By way of background, Premarket Approval ("PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. According to the FDA, Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

99. PMA is intended to be a stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA.

100. An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device if it complies with federal laws and is not "adulterated" or "misbranded".

101. FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's Recommendation on whether the FDA should approve the submission.

102. However, the PMA process for Essure was "expedited", and several trial candidates' medical records were altered to reflect favorable data.

103. According to the FDA, a Class III device that fails to meet CPMA requirements is considered to be adulterated under section 501(f) of the FDCA and cannot be marketed, distributed, or advertised under 21 C.F.R. 814.80.

104. Regarding the PMA, devices can either be "approved", "conditionally approved," or "not approved."

105. Essure was "conditionally approved". It had CPMA, not PMA, which is the "gold standard".

106. In the CPMA Order issued by the FDA, the FDA expressly stated, "Failure to comply with the conditions of approval invalidates this approval order[1]." The following were conditions of approval:

a. "Effectiveness of Essure is established by annually reporting on the 745 women who took part in clinical tests."

[1] Note: The CPMA order does not read…failure to comply *may* invalidate the order.

b. "Successful bilateral placement of Essure is documented for newly trained physicians."

c. "Within 10 days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

d. "Report to the FDA whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

e. Warranties are truthful, accurate, and not misleading.

f. Warranties are consistent with applicable federal and state law.

g. Conduct a post approval study in the United States to document the bilateral placement rate for newly trained physicians.

h. Include results from the annual reporting on the patients who took part in the Pivotal and Phase II clinical investigations in the labeling as these data become available.

i. Submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

j. Submit a PMA supplement whenever there are changes to the performance of the device.

V

REQUIREMENTS UNDER FEDERAL REGULATIONS

107. The CPMA also required Defendant to comply with the Medical Device Reporting regulations and post market requirements for Class III medical devices:

a. Report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device may have caused or contributed to serious injury;

b. Report to the FDA within thirty (30) days whenever they receive notice of serious injury;

c. Report to the FDA information suggesting that one of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, 21 CFR §§ 803.50 et seq.;

d. Monitor the product after pre-market approval and discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;

e. Submit a PMA Supplement for any change in manufacturing site, 21 CFR §§ 814.39 et seq.;

f. Establish and maintain quality system requirements to ensure that quality requirements are met, 21 CFR § 820.20 et seq.;

g. Establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use

conditions, creation of a risk plan, and conducting risk analyses, 21 CFR §§ 820.30 et seq.;

h. Document all Corrective Action and Preventative Actions taken by the manufacturer to address non-conformance and other internal quality control issues, 21 CFR §§ 820.100 et seq.;

i. Establish internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq. and §§ 820.20 et seq.;

j. Establish Quality Management System (QMS) procedures to assess potential causes of non-conforming products and other quality problems, 21 CFR §§820.70 et seq. and 21 CFR §§ 27 820.90 et seq.;

k. Report on Post Approval Studies in a timely fashion, 21 CFR §§ 814.80;

l. Advertise the device accurately and truthfully, 21 CFR §§ 801 et seq.

108. Defendant was also, at all times, responsible for maintaining the labeling of Essure. Accordingly, Defendant had the ability to file a "Special PMA Supplement – Changes Being Effected" ("CBE") which allows the Defendant to unilaterally update the labeling of Essure to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d). These changes include:

a. Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. Labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

109. Upon obtaining knowledge of these potential device failure modes, Defendant was required under the Essure CPMA, 21 CFR §§820.30 et seq., 21 CFR §§ 820.100 et seq., and the FDA Recognized Consensus Standard ISO 14971, to use this information to routinely update the risk analyses for the Essure device and take any and all Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Defendant was required to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects. 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq.

VI

FAILURES OF ESSURE

110. After obtaining the CPMA, Defendant became aware of potential quality and failure modes associated with Essure and failed to warn Plaintiffs and/or their implanting

physicians. Defendant became aware that the following failures could occur with the device and lead to adverse consequences for the patient:

a. The stainless steel used in Essure can become un-passivated, which allows it to rust and degrade;

b. The nitinol could have a nickel rich oxide, which the body attacks;

c. The "no lead" solder could, in fact, have trace lead in it;

d. The Galvanic action between the metals used to manufacture Essure, which causes the encapsulation of the product within the fallopian tubes, could be a continuous irritant to some patients;

e. The nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;

f. Latent manufacturing defects, such as cracks, scratches, and other disruption of the smooth surface of the metal coil, may exist in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;

g. Degradation products of polyethylene terephthalate (PET) used in the implant can be toxic to patients, inciting both chronic inflammation and endocrine and autoimmune diseases or symptoms; and

h. PET fibers are also known endocrine disruptors. Endocrine Disrupting Chemicals ("EDCs") like PET often disrupt endocrine systems by mimicking or blocking a natural hormone. In the case of hormone mimics, an EDC can "trick" that hormone's receptor into thinking that the EDC is

the hormone, and this can inappropriately activate the receptor and trigger processes normally activated only by a natural hormone.

i. PET fibers found on the Essure device (that were intended to cause an inflammatory response) are also causing endocrine disruption which has "unmasked" and caused autoimmune diseases and other autoimmune like symptoms in women who have been implanted with the Essure device.

j. The mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body.

VII

VIOLATIONS OF FEDERAL REQUIREMENTS

111. In June 2002, the FDA found the following objectionable conditions:

a. Design outputs were not completely identified.

b. Corrective and preventative action activities were not being documented, including implementation of corrective and preventative actions.

c. Procedures addressing verification of corrective and preventative actions were not implemented.

112. In July 2002, during an inspection of Defendant's facility, the FDA observed that adverse events were not captured in the data.

113. In July of 2002, the FDA found that:

a. Defendant "does not have an assurance/quality control unit".

114. In June 2003, the following observations were made by the FDA which resulted in the FDA issuing Form 483s:

a. Two lot history records showed rejected raw materials which was not documented and, therefore, could not be tracked.

b. Procedures were not followed for the control of products that did not conform to specifications.

115. In December 2010, the FDA found that Defendant was "not reporting complaints of their product being seen radiographically in the patient's abdominal cavity" and "did not have a risk analysis of the coils being in the abdominal cavity".

116. Defendant failed to comply with several conditions, including:

a. Defendant failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendant also failed to timely submit post approval reports for its six month, one year, eighteenth month and two year reports. All reports failed to meet the respective deadlines.

b. Defendant failed to document successful placement of Essure, concealing the failure rates.

c. Defendant failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report eight (8) perforations, which occurred as a result of Essure, and was cited for the same by the FDA via Form 483.[2]

[2] Form 483 is issued to firm management at the conclusion of inspections when an FDA investigator has observed any conditions that violate the FDCA rendering a device "adulterated".

d. Defendant failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury, concealing the injuries. Again, Defendants failed to report eight (8) perforations which occurred as a result of Essure to the FDA as evidenced in Form 483.

e. As outlined *infra*, Defendant's warranties were not truthful or accurate, and were, in fact, misleading.

f. Defendant's warranties were not consistent with applicable federal and state law.

g. Defendant failed to notice the FDA of their internal Excel file containing 16,047 entries of complaints.

117. Defendant was also found to be:

a. Erroneously using non-conforming material in the manufacturing of Essure and not tracking where it went.

b. Failing to use pre-sterile and post-sterile cages.

c. Manufacturing Essure at an unlicensed facility.

d. Manufacturing Essure for three years without a license to do so.

e. Not reporting … complaints in which their product migrated.

f. Not considering these complaints in their risk analysis for the design of Essure.

g. Failing to document CAPA activities for a supplier corrective action.

118. Specifically, it was determined that:

a. On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes. Defendant was issued these violations for dates of incidents 5/11/10, 9/1/10, 10/1/10, 10/5/10, 10/26/10, 11/3/10, 11/5/10, and 11/16/10.

b. Defendant had notice of 168 perforations, but only disclosed 22 to the FDA.

c. On January 6, 2011, Defendant was cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure did not include, as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

d. On January 6, 2011, Defendant was cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendant's design. The FDA also found that Defendant's CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendant's engineers learned of this, and it was not documented.

e. On July 7, 2003, Defendant was cited for not analyzing and identifying existing and potential causes of non-conforming product and other quality

problems. Specifically, two lot history records showed rejected raw material was not documented on a quality assurance form which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

f. On July 7, 2003, Defendant was cited for not following procedures used to control products which did not conform to specifications.

119. In response, Defendant admitted that "the device may have caused or contributed to a death or serious injury, and an MDR Report is required to be submitted to FDA".

120. In addition, Defendant's failure to timely file MDRs and to report to the FDA the complaints that were not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency, which it knew of from the more than 32,000 complaints it received, violated the CPMA, FDA post-marketing regulations and parallel state law.

121. Moreover, Defendant did not provide the requisite training to the implanting physicians prior to selling it to the same.

VIII

FDA HEARINGS AND RESULTING ACTION

122. Defendant's conduct not only violated its federal regulatory duties and its duties under state law, but also caused a massive failure of information that has to be present in the medical and scientific community to protect a patient's interest. Because Defendant failed to

timely, completely, or accurately report their knowledge of the risks and complications associated with the Essure device, the public's knowledge of the risks associated with Essure were seriously hampered and delayed. This endangered patient safety, including Plaintiffs' safety.

123. As the FDA continued to force the Defendant to provide additional information known to them that had been withheld, more information belatedly was made known to the medical community, including information concerning the frequency, severity, and permanence of complications associated with the prescription and implementation of Essure.

124. This belated and untimely release of relevant and important information lead to an increasing number of adverse events being reported to the FDA about Essure from patients and physicians. Because of these complaints, the FDA convened a public hearing concerning the safety and efficacy of Essure. At that hearing, the Defendant continued to misrepresent the safety and efficacy of Essure. For example, the Defendant stated:

a. The efficacy rates for Essure are 99.6%; in reality, studies show that the chances of becoming pregnant with Essure are higher than with tubal ligations and higher than the rates reported by Bayer to the FDA at the public hearing;

b. Defendant testified that skin patch testing is not a reliable predictor of clinically significant reactions to nickel-containing implantable devices, including Essure. Despite this, Bayer told physicians and patients that a nickel sensitivity test was sufficient to determine whether a patient was a suitable candidate for an Essure device;

c. Defendant testified that "[a]s an alternative to Essure, laparoscopic tubal ligation is a safe and effective method of permanent birth control". In

reality, studies show that the chances of becoming pregnant with Essure are higher than with tubal ligations, and Essure patients are much more likely to require additional surgeries to correct complications associated with the sterilization procedure;

d. Defendant testified that most of the reports of adverse events to the FDA have come from consumers and not Defendant, which is unusual. In reality, the Defendant failed to report thousands of complaints of adverse events that it had received.

125. On February 29, 2016, the FDA first publicly announced "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device. The FDA took the following actions:

a. The FDA is requiring a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions". The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device."

b. The FDA is requiring Defendant to implement a Patient Decision Checklist "to help to ensure women receive and understand information regarding the benefits and risks" of Essure. The FDA's draft Patient Decision Checklist is a five-page document that the physician will discuss with each patient interested in using the device. The patient must initial after each topic of discussion, and both the physician and patient must sign the document. The topics for discussion include, *inter alia*, the risks for "adverse events including persistent pain, device puncture of the uterus and/or fallopian tubes ('perforation'), or movement of the device into the

abdomen or pelvis ('intra-peritoneal migration')"; "allergy or hypersensitivity reactions"; symptoms such as changes in the skin (rash, itching), "chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting"; "joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes"; the fact that "there is no reliable test to predict ahead of time who may develop a reaction to the device"; the possibility that the Essure device "can move after placement," possibly becoming ineffective at preventing pregnancy or leading to "serious adverse events such as bleeding or bowel damage, which may require surgery to address"; and the fact that if the Essure device has to be removed after placement, it will require surgery to remove and, possibly, a hysterectomy.

c. The FDA has also ordered Bayer "to conduct a new post-market surveillance study designed to provide important information about the risks of the device in a real-world environment". The study must provide data on "the risks associated with Essure® and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure® device. The study will also evaluate how much these complications affect a patient's quality of life. . . .The FDA will use the results of this study to determine what, if any, further actions related to Essure® are needed to protect public health."

126. Unfortunately, this new warning, labeling, and patient decision checklist came too late to warn Plaintiffs of the true risks of Essure. Had the Defendant complied with their federal regulatory duties and their duties under state law by reporting the known risks and complications in a timely fashion, Plaintiffs and their physicians would have had this relevant, critical information available to them prior to the implant of Essure. At all relevant times, Defendant's Essure product was prescribed and used as intended by Defendants and in a manner reasonably

foreseeable to Defendant. Moreover, Defendant's misrepresentations regarding Essure discussed *infra*, in effect, over-promoted Essure and nullified otherwise adequate warnings.

127. Lastly, although Essure appears at first glance to be a "medical device", Defendant actually categorizes it as a "drug".

128. In short, Essure is considered an "adulterated" and "misbranded" product that could not have been marketed or sold to Plaintiffs per the FDA and federal law, and all of Plaintiffs' claims center around violations of the CPMA requirements and/or federal regulations and statutes.

IX

DEFENDANT'S TRAINING AND DISTRIBUTION PLAN

129. Defendant (1) failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians; (2) provided specialized hysteroscopic equipment to the implanting physicians who were not qualified or competent to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiffs' safety and well-being.

130. Because Essure was the first device of its kind, the implanting physicians were trained by Defendant on how to properly insert the micro-inserts using the disposable delivery system and were given hysteroscopic equipment by Defendant.

131. In order to capture the market, Defendant independently undertook a duty of training physicians outside of FDA guidelines, including the implanting physicians, on how to

properly use its own mechanism of delivery and the specialized hysteroscopic equipment manufactured by a third party.

132. Defendant's Senior Director of Global Professional Education stated, "training is the key factor when clinicians choose a new procedure" and, "For the Essure procedure, the patient is not under anesthesia, therefore a skilled approach is crucial."

133. In fact, because gynecologists and Plaintiffs' implanting physicians were unfamiliar with the device and how to deliver it, Defendant (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendant observed physicians until Defendant believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiffs that "Physicians must be signed-off to perform Essure procedures."

134. Defendant provided no training to the implanting physicians on how to remove Essure should it fail.

135. Defendant also kept training records on all physicians "signed-off to perform Essure procedures".

136. In order to sell its product and because the implanting physicians did not have access to the expensive hysteroscopic equipment, Defendant provided the implanting physicians with hysteroscopic equipment which, although is not a part of Essure, is needed to implant Essure. The entrustment of this equipment is not part of any CPMA.

137. In fact, Defendant entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy, America, Inc. to obtain specialized hysteroscopic equipment to then give to physicians and to increase its sales force to promote Essure.

138. According to Defendant, these agreements allowed Defendant to "gain market presence…and expand … market opportunity by driving adoption among a group of physicians".

139. In regard to the entrustment of such specialized equipment, Defendant admitted: "We cannot be certain how successful these programs will be, if at all."

140. Defendant "handed out" this hysteroscopic equipment to unqualified physicians, including Plaintiffs' implanting physicians, in an effort to sell its product.

141. Defendant knew or failed to recognize that the implanting physicians were not qualified to use such specialized equipment yet provided the equipment to the unqualified implanting physicians in order to capture the market.

142. In return for providing the expensive hysteroscopic equipment, Defendants required that the implanting physicians purchase two Essure "kits" per month. This was part of Defendant's unreasonably dangerous and negligent distribution plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiffs.

143. The physicians had to purchase the kits regardless of whether they used them or not. This distribution plan created an environment which induced the implanting physicians to "push" Essure and implant the same into Plaintiffs.

144. Defendant used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as bait. Once the implanting physicians "took the bait", they were required to purchase two (2) Essure "kits" per month, regardless of whether they sold any Essure "kits".

145. Defendant's distribution plan also included (1) negligently distributing Essure in violation of FDA orders and federal regulations; (2) marketing and selling an "adulterated" and "misbranded" product; (3) promoting Essure through representatives of the hysteroscopic equipment manufacturers who were not adequately trained, nor had sufficient knowledge regarding Essure; (4) failing to report and actively concealing adverse events which occurred as a result of Essure; (5) erroneously using non-conforming material and failing to keep track of the same in the manufacturing of Essure; (6) failing to use pre-sterile and post-sterile cages; (7) manufacturing Essure at an unlicensed facility; and (8) manufacturing Essure for three years without a license to do so.

146. In short, Defendant (1) failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use it; and (3) created an unreasonably dangerous distribution and reporting plan aimed at capitalizing and monopolizing the birth control market.

147. All of this was done in violation of federal law and its CPMA. Unfortunately, this was done at the expense of Plaintiffs' safety.

X

PLAINTIFFS' HISTORIES

148. As discussed in depth below, each of the Plaintiffs in this case has sustained serious physical injuries as a result of being implanted with the permanent birth control device, Essure®. As a result of (1) Defendant's negligence described *infra*; and (2) Plaintiffs' reliance on defendant's warranties, Defendant's Essure® devices have caused Plaintiffs serious personal injuries. As such, Plaintiffs have suffered a range of injuries such as ectopic pregnancy, actual pregnancy, abdominal pain, depression, fatigue, heavy bleeding, pain during intercourse, weight fluctuations, severe back pain, and migraines. Additionally, some Plaintiffs' Essure® devices have migrated, perforated, and even become embedded in areas outside of the fallopian tubes. Moreover, some Plaintiffs have been forced to undergo hysterectomies in an effort to have their Essure® devices removed.

A. ARIZONA

1. Madlyne Bobo

152. Madlyne Bobo is a resident of Florence, Arizona.

153. In or around May 2007, Plaintiff Madlyne underwent the Essure® procedure at Banner Hospital in Mesa, Arizona.

154. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, abdominal pain, and hormonal fluctuations.

155. On or about April 21, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at Chandler Regional Hospital in Chandler, Arizona.

156. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

B. CALIFORNIA

1. Ema Hernandez

157. Ema Hernandez is a resident of Gardena, California.

158. In or around August 2014, Plaintiff Ema Hernandez underwent the Essure® procedure at Kaiser Permanente in Bellflower, California.

159. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

160. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, severe abdominal pain, cramping, bloating, pain during intercourse, hormonal fluctuations, and severe anemia.

161. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

162. Plaintiff is scheduled to undergo a hysterectomy to remove the Essure® device at Kaiser Permanente in Harvard City, California on September 15, 2017.

163. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Ronald Hughes

164. Ronald Hughes is a resident of Gardena, California.

165. Ronald Hughes is married to Plaintiff Ema Hernandez and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

166. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

167. Plaintiff's wife experienced constant pain, mood swings, and depression.

168. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

169. Additionally, after Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

170. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

171. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. Dawn Carpenter

172. Dawn Carpenter is a resident of San Bernardino, California.

173. In or about November 2007, Plaintiff Dawn Carpenter underwent the Essure® procedure at Kaiser Permanente-Fontana Medical Center.

174. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

175. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer unusual bleeding, cramping, prolonged menstruation, severe abdominal pain, hormonal fluctuations, and developed ovarian cysts.

176. Plaintiff also experienced device migration and organ perforation.

177. On or about March 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at Kaiser Permanente-Fontana Medical Center in Fontana, California by Dr. Alin Ionescu.

178. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. Richard Carpenter

179. Plaintiff Richard Carpenter is a resident of San Bernardino, California

180. Plaintiff Richard Carpenter is married to Plaintiff Dawn Carpenter and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

181. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

182. Plaintiff's wife experienced unusual bleeding, cramping, prolonged menstruation, severe abdominal pain, hormonal fluctuations, ovarian cysts, device migration and organ perforation.

183. After Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

184. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

185. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

186. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

5. Odessa Charboneau

187. Odessa Charboneau is a resident of Biggs, California.

188. On or about March 2012, Plaintiff Odessa Charboneau underwent the Essure® procedure at Planned Parenthood.

189. Shortly after undergoing the Essure® procedure, Plaintiff experienced device migration and unintended pregnancy. suffered from organ perforation.

190. Plaintiff also experienced organ perforation.

191. In or about June of 2012, Plaintiff underwent removal of device at Enloe Medical Center in Chico, California.

192. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and,

based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have no choice but to undergo a hysterectomy to have her Essure® removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

6. Ronnine Hernandez

193. Ronnie Hernandez is a resident of Elk Grove, California.

194. On or about April 11, 2012, Plaintiff Ronnine Hernandez underwent the Essure® procedure at Kaiser Permanente South Sacramento Medical Center in Sacramento, California by Dr. Jennifer Sheppard.

195. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

196. Shortly after undergoing the Essure® procedure, Plaintiff began to unusual bleeding, pelvic pain, severe abdominal pain, migraines, unusual periods, and painful intercourse.

197. On or about June 2016, Plaintiff underwent removal of device at Kaiser Permanente South Sacramento Medical Center in Sacramento, California.

198. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and,

based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have no choice but to undergo a hysterectomy to have her Essure® removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

7. Cynthia Boyd

199. Cynthia Boyd is a resident of Santa Monica, California. In or about December 2012, Plaintiff Cynthia Boyd underwent the Essure® procedure at Dr. Kim Dillion's s office located in Santa Monica, California.

200. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer serious infections resulting in prolonged hospitalization, heavy and unusual bleeding, severe abdominal pain, nausea, pelvic pain, hormonal fluctuations, bloating, and severe fatigue.

201. Plaintiff was diagnosed with fibromyalgia after being implanted with the Essure® device.

202. Plaintiff is scheduled to undergo an hysterectomy to remove the Essure® device on August 30, 2017 by Dr. Carol Karamitsos at Marin Regional Medical Center in Santa Monica, California.

203. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

C. FLORIDA

1. Georgia Benjamin

204. Georgia Benjamin is a resident of Clermont, Florida.

205. In or about May 2012, Plaintiff Georgia Benjamin underwent the Essure® procedure at St. John's Riverside Hospital in Yonkers, New York.

206. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer irregular and prolonged menstruation, severe menstruation pain, heavy and abnormal menstruation, severe abdominal pain, pain during intercourse, severe abdominal pain, cramping and bloating.

207. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines - for which she had no history of suffering prior to undergoing the implantation of Essure®.

208. Additionally, Plaintiff underwent hysterectomy in or about June 2016 at South Lake Hospital in Claremont, Florida to remove the Essure® device.

209. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Shania Clarke

210. Shania Clarke is a resident of Deland, Florida.

211. In or about July 2010, Plaintiff Shania Clarke underwent the Essure® procedure at Feldman Jacinta CNM Obstetrics and Gynecology in Deland, Florida by Dr. Stanley Gelman.

212. Shortly after undergoing the Essure® procedure, Plaintiff experienced an unintended pregnancy.

213. In or about October 2011, Plaintiff underwent a hysterectomy to remove the Essure® device at Dr. Jeffrey Brooks' practice located in Deland, Florida.

214. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Christy Turner

215. Christy Turner is a resident of River Beach, Florida.

216. In or about April 2013, Plaintiff Jennifer Gonzalez underwent the Essure® procedure at Obstetrics and Gynecology Specialists in West Palm Beach, Florida by Dr. Robert Gordon.

217. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

218. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstruation pain, irregular and prolonged menstruation, heavy and abnormal menstruation, pain during intercourse, hormonal fluctuations, depression, and back pain.

219. Plaintiff also experienced device migration and device fracture.

220. In or around December 2013, Plaintiff underwent a partial hysterectomy to remove the Essure® device at Palms West Hospital in Loxahatchee, Florida by Dr. Sarah Bernstein.

221. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. Mischell Hall

222. Mischell Hall is a resident of Jacksonville, Florida.

223. In or about October 2015, Plaintiff Mischell Hall underwent the Essure® procedure at North Florida Obstetrics and Gynecology in Jacksonville, Florida by Dr. Thomas Virtue.

224. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstruation pain, irregular and prolonged menstruation, heavy and abnormal menstruation, hormonal fluctuations, cramping, and bloating.

225. After undergoing the Essure® procedure Plaintiff has also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

226. In or around October 2013, Plaintiff underwent a hysterectomy to remove the Essure® device at St. Vincent Hospital in Jacksonville, Florida by Dr. Thomas Virtue.

227. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

D. GEORGIA

1. Casaundra Wiggins

228. Casaundra Wiggins is a resident of Douglasville, Georgia.

229. In or about April 2012, Plaintiff Casaundra Wiggins underwent the Essure procedure at Wellstar Medical Group South Cobb OB/GYN in Douglasville, Georgia by Dr. Milele Francis.

230. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer heavy and abnormal menstruation, severe abdominal pain, cramping and bloating, low blood levels, and blurred vision.

231. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

232. On June 15, 2017, Plaintiff underwent a hysterectomy at Wellstar Medical Group Cobb OB/GYN in Austell, Georgia to remove the Essure® device, and cancerous cells.

233. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied, to her detriment, on Defendant's misrepresentations concerning Essure®.

2. Elisha Wilborn

234. Elisha Wilborn is a resident of Ellenwood, Georgia.

235. In or about May 2010, Plaintiff Elisha Wilborn underwent the Essure® procedure at Premier Women's Healthcare Center in Lithonia, Georgia by Dr. Dominique Smith.

236. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

237. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstruation pain, irregular and prolonged menstruation, heavy and abnormal menstruation, pain during intercourse, and hormonal fluctuations.

238. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

239. Plaintiff also experienced unintended pregnancies resulting in miscarriages, device migration, device fracture, and organ perforation.

240. On or about June 22, 2017, Plaintiff was advised by Dr. Kevin Edmonds that the complications Plaintiff experienced were as a result of the Essure® device.

241. On or about July 25, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at Piedmont Henry Hospital in Stockbridge, Georgia by Dr. Kevin Edmonds.

242. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen

to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

E. ILLINOIS

1. Stephanie Loucks

243. Stephanie Loucks is a resident of Steeleville, Illinois.

244. On or about August 10, 2011, Plaintiff Stephanie Loucks underwent the Essure® procedure at New Horizons Obstetrics and Gynecology in Carbondale, Illinois by Dr. Frank Walker.

245. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer heavy and abnormal bleeding, severe abdominal pain, hormonal fluctuations, cramping, bloating, painful intercourse, and developed a blood disorder.

246. After undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

247. On or about September 2016, Plaintiff underwent a hysterectomy to remove the Essure® at New Horizons Obstetrics and Gynecology Carbondale, Illinois by Dr. Andre Bobo. Plaintiff experienced severe complications during the procedure including but not limited to blood loss and cardiac arrest requiring resuscitation.

248. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control.

249. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Dustin Loucks

250. Plaintiff Dustin Loucks is a resident of Steeleville, Illinois.

251. Plaintiff Dustin Loucks is married to Plaintiff Stephanie Loucks and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

252. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

253. Plaintiff's wife experienced heavy and abnormal bleeding, severe abdominal pain, hormonal fluctuations, migraines, cramping, bloating, and painful intercourse.

254. After Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

255. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

256. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

257. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. Dyanna Lucas

258. Dyanna Lucas is a resident of Mattoon, Illinois.

259. In or about June 2013, Plaintiff Dyanna Lucas underwent the Essure® procedure at Planned Parenthood in Chicago, Illinois.

260. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

261. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer unusual periods, severe abdominal pain, cramping, bloating, and pain during intercourse.

262. Additionally, after undergoing the Essure® procedure Plaintiff suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

263. Plaintiff also experienced device migration.

264. In or about June 2015, Plaintiff underwent removal of the Essure® device at Women's Health Clinic in Illinois.

265. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen

to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. Michelle Vaughn

266. Michelle Vaughn is a resident of Aurora, Illinois.

267. On or about April 22, 2009, Plaintiff Michelle Vaughn underwent the Essure® procedure at Copley Memorial Hospital in Aurora, Illinois by Dr. Rochelle Wilburn.

268. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer lower back pain, cramping, bloating, hormonal fluctuations, and painful intercourse.

269. Plaintiff also experienced device migration and organ perforation.

270. In or about August 2009, Plaintiff underwent removal of the Essure® device at Copley Memorial Hospital in Aurora, Illinois.

271. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

F. KENTUCKY

1. Eugena Davis

272. Eugena Davis is a resident of Louisville, Kentucky.

273. On or about June 2014, Plaintiff Eugena Davis underwent the Essure® procedure at Baptist Health in East Louisville, Kentucky by Dr. Margarita Terrassa.

274. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer heavy and abnormal menstruation, cramping, bloating, vaginal and bacterial infections.

275. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

276. On or about September 2014, Plaintiff underwent hysterectomy at Baptist East Louisville, Kentucky to remove the Essure® device.

277. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Reco Davis

278. Plaintiff Reco Davis is a resident of Louisville, Kentucky.

279. Plaintiff Reco Davis is married to Plaintiff Eugena Davis and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

280. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

281. Plaintiff suffered lost wages because he would have to leave work and come home early to take care of his wife when she was in pain.

282. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

283. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

284. Plaintiff took his wife to and from doctor's appointments on several occasions, and tended to her well-being as she recovered from a hysterectomy.

285. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

G. LOUISIANA

1. Shareka Carley

286. Shareka Carley is a resident of Shreveport, Louisiana.

287. In or about June 2009, Plaintiff Shareka Carley underwent the Essure® procedure at University Health in Shreveport, Louisiana.

288. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

289. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe abdominal pain, cramping, bloating, hormonal fluctuations, and an unintended pregnancy.

290. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

291. Plaintiff also experienced device migration and device fracture.

292. In or around January 2015, Plaintiff underwent a partial hysterectomy to remove the Essure® device at University Health in Shreveport, Louisiana.

293. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

H. MASSACHUSETTS

1. Weina Sampson

294. Weina Sampson is a resident of Holden, Massachusetts.

295. In or about February of 2012, Plaintiff Weina Sampson underwent the Essure® procedure at Central Mass OBGYN Associates in Shrewsbury, Massachusett by Dr. Maria Narducci.

296. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer heavy and abnormal menstruation, severe abdominal pain, and device migration.

297. In or around December 2013, Plaintiff underwent a surgery to remove the Essure® device at the University of Massachusetts Memorial Medical Center – Memorial Campus by Dr. Maria Narducci. Only a portion of the device could be removed. The remaining portion of the Essure® device remains embedded in the Plaintiff's uterus.

298. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have to undergo a hysterectomy to completely remove the device. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

I. MICHIGAN

1. Jacklyn Gerlach

299. Jacklyn Gerlach is a resident of Flint, Michigan.

300. In May of 2014, Plaintiff Jacklyn Gerlach underwent the Essure® procedure at Genesys Hospital in Grand Blanc, Michigan.

301. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, abdominal pain, cramping, bloating, hormonal fluctuations, and pain during intercourse.

302. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

303. Plaintiff also experienced device migration.

304. In or about June of 2016, Plaintiff underwent a partial hysterectomy to have the Essure® device removed at Genesys Hospital in Grand Blanc, Michigan.

305. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Ellen Ball

306. Ellen Ball is a resident of Taylor, Michigan.

307. On or about November 16, 2011, Plaintiff Ellen Ball underwent the Essure® procedure at Downriver Obstetrics and Gynecology in Michigan by Dr. Salvataore Finazzo.

308. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

309. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstruation pain, heavy and abnormal menstruation, pain during intercourse, and severe abdominal pain.

310. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

311. On or about May 16, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at Henry Ford Wyandotte Hospital in Wyandotte, Michigan by Dr. Salvataore Finazzo.

312. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Domonique Dantzler

313. Domonique Dantzler is a resident of Detroit, Michigan.

314. On or about November 2014, Plaintiff Domonique Dantzler underwent the Essure® procedure.

315. The procedure was performed at Botsford Hospital in Farmington Hills, Michigan.

316. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe abdominal pain, lower back pain, a rash on her left inner arm, and a metal taste in her mouth.

317. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

318. On June 18, 2017, Plaintiff underwent a partial hysterectomy in order to have the Essure® device removed.

319. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

J. MISSISSIPPI

1. Tiffany Messenger

320. Tiffany Messenger is a resident of Clarksdale, Mississippi.

321. In or about May 2007, Plaintiff Tiffany Messenger underwent the Essure® procedure at Northwest Mississippi Regional Medical Center in Clarksdale, Mississippi.

322. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, heavy and abnormal bleeding, irregular and prolonged menstruation.

323. Additionally, Plaintiff suffered from device migration and organ perforation and required surgery to remove implants.

324. As a result of the complications Plaintiff was experiencing, in or about March 2017, Plaintiff underwent a surgery to remove the Essure® device at Northwest Mississippi Regional Medical Center in Clarksdale, Mississippi.

325. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

K. MISSOURI

1. Andrea Wilkinson

326. Andrea Wilkinson is a resident of Jackson, Missouri.

327. In or about December 2008, Plaintiff Andrea Wilkinson underwent the Essure® procedure at Doctor's Park Surgery, Inc. in Cape Girardeau, Missouri by Dr. Tammy Williams.

328. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

329. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer menstrual pain, heavy and abnormal bleeding, severe abdominal pain, cramping, bloating, and pain during intercourse.

330. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

331. In or about October 2014, Plaintiff underwent a hysterectomy to remove the Essure® device at Saint Francis Medical Center in Cape Girardeau, Missouri by Dr. Kimberly Roof.

332. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

L. NEW MEXICO

1. Monique Quevedo

333. Monique Quevedo is a resident of Albuquerque, New Mexico.

334. In or about April 2010, Plaintiff Monique Quevedo underwent the Essure® procedure at Presbyterian Hospital in Albuquerque, New Mexico.

335. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

336. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, cramping, bloating, hormonal fluctuations, and pain during intercourse.

337. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

338. On or about July 28, 2014, Plaintiff underwent a hysterectomy to remove the Essure® device at Presbyterian Hospital in Albuquerque, New Mexico by Dr. Raymond Elmore.

339. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

M. NEW YORK

1. Shannon Golden

340. Shannon Golden is a resident Ridge, New York.

341. In or around November 2012, Plaintiff Shannon Golden underwent the Essure® procedure at Stony Brook University Medical Center in East Setauket, New York.

342. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer heavy and abnormal menstruation, and serious infections resulting in prolonged hospitalization.

343. Additionally, Plaintiff suffered device migration.

344. Patient also experienced two dilation and curettage procedures.

345. On or about August 2014, Plaintiff underwent a hysterectomy to remove the Essure® device at John T Mather Memorial Hospital in New York by Dr. Michael Arato.

346. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®.

347. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Michael Golden

348. Plaintiff Michael Golden is a resident of Ridge, New York.

349. Plaintiff Michael Golden is married to Plaintiff Shannon Golden and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

350. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

351. Plaintiff's wife began to suffer heavy and abnormal menstruation, and serious infections resulting in prolonged hospitalization.

352. After Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

353. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

354. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

355. Observing his wife in pain and assuming the role of caretaker also caused Plaintiff to develop depression and experience mood swings.

356. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. Jane Cuevas

357. Jane Cuevas is a resident of New York, New York.

358. In or around April 2004, Plaintiff Jane Cuevas underwent the Essure® procedure at New York Presbyterian Hospital in Broadway, New York, by Dr. Ann Davis.

359. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, cramping, bloating, hormonal fluctuations, pain in her left ovary, and serious infections.

360. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

361. Additionally, Plaintiff suffered from device migration.

362. In or about January 2006, Plaintiff underwent a partial hysterectomy at New York Presbyterian Hospital in New York, New York.

363. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

N. NORTH CAROLINA

1. Daryale Franklin

264. Daryale Franklin is a resident of Pineville, North Carolina.

265. In or around May 2014, Plaintiff Daryale Franklin underwent the Essure® procedure at Bronson Methodist Hospital in Kalamazoo, Michigan.

266. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

267. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer heavy and abnormal menstruation, severe abdominal pain, pain during intercourse and joint pain.

268. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

269. Additionally, Plaintiff suffered from device migration.

270. On or about January 21, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at Bronson Methodist Hospital in Kalamazoo, Michigan.

271. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Jarmain Franklin

272. Plaintiff Jarmain Franklin is a resident of Pineville, North Carolina.

273. Plaintiff Jarmain Franklin is married to Plaintiff Daryale Franklin and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

274. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

275. After the Plaintiff's wife underwent the Essure® implant, Plaintiff's wife began experiencing debilitating abdominal pain, migraines, and joint pain on a daily basis.

276. Plaintiff became primarily responsible for tending to all household chores.

277. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

278. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

279. Plaintiff was subsequently fired from his job for taking too much time off work to tend to his ill wife.

280. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. Rosena Patterson

281. Rosena Patterson is a resident of Matthews, North Carolina.

282. 343. On or about April of 2014, Plaintiff Rosena Patterson underwent the Essure® procedure at Novant Health - Southeast in Matthews, North Carolina.

283. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe abdominal pain and organ perforation

284. Plaintiff also experienced device migration.

285. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

286. On or about October of 2014, Plaintiff underwent a hysterectomy to remove the Essure® device at Novant Health Presbyterian Medical Center in Matthews, North Carolina.

287. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

O. OHIO

1. Darlene Verno

388. Darlene Verno is a resident of Humbard, Ohio.

389. On June 21, 2006, Plaintiff Darlene Verno underwent the Essure® procedure.

390. The procedure was performed at UPMC Horizon Hospital in Farrell, Pennsylvania by Dr. Michael Abdul-Malak.

391. Immediately after undergoing the Essure® procedure, Plaintiff began to suffer extreme lower back pain, and cramping.

392. Additionally, Plaintiff suffers from irregular and prolonged menstruation, heavy bleeding, and painful intercourse.

393. Plaintiff has experienced device migration from her right fallopian tube to her uterus where the device is currently embedded.

394. Plaintiff's hysterectomy is currently scheduled to occur in October 2017.

395. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Jacqueline Gose

396. Jacqueline Gose is a resident of Akron, Ohio.

397. In or about June 2007, Plaintiff Jacqueline Gose underwent the Essure® procedure at Fairfield OBGYN Associates in Lancaster, Ohio by Dr. James Guenther.

398. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer unusual bleeding, pelvic pain, and abdominal pain.

399. On or about September 2013, Plaintiff underwent a hysterectomy to remove the Essure® device at Summa Akron City Hospital in Akron, Ohio.

400. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Michele Burke

401. Michelle Burke is a resident of Cincinnati, Ohio.

402. In or about September 2014, Plaintiff Michelle Burke underwent the Essure® procedure at The Christ Hospital in Cincinnati, Ohio.

403. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

404. Shortly after undergoing the Essure® procedure, Plaintiff began to irregular and prolonged menstruation, heavy and abnormal menstruation, pain during intercourse, severe abdominal pain, cramping, bloating, back pain, and weight gain.

405. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

406. Plaintiff also experienced device migration.

407. On June 15, 2016, Plaintiff underwent a hysterectomy to remove the Essure® device at Good Samaritan Hospital in Cincinnati, Ohio.

408. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. Daniel Burke

409. Plaintiff Daniel Burke is a resident of Cincinnati, Ohio.

410. Plaintiff Daniel Burke is married to Plaintiff Michelle Burk and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

411. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

412. Plaintiff's wife experienced irregular and prolonged menstruation, heavy and abnormal menstruation, pain during intercourse, severe abdominal pain, cramping, bloating, back pain, and weight gain.

413. After Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

414. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

415. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

416. Observing his wife in pain and assuming the role of caretaker also caused Plaintiff to develop depression and experience mood swings.

417. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

5. Keauna Felton

418. Keauna Felton is a resident of Dayton, Ohio.

419. In or about August 2008, Plaintiff Keauna Felton underwent the Essure® procedure at Miami Valley Hospital in Dayton, Ohio.

420. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

421. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer prolonged menstruation, severe menstruation pain, abnormal menstruation, pain during intercourse, and cramping.

422. Plaintiff also experienced device migration and organ perforation.

423. In or about July 2012, Plaintiff underwent a hysterectomy to remove the Essure® device at Southview Medical Center in Dayton, Ohio.

424. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

P. PENNSYLVANIA

1. Amanda Burns

425. Amanda Burns is a resident of Warminster, Pennsylvania.

426. On July 25, 2011, Plaintiff Amanda Burns underwent the Essure® procedure at Abington OBGYN Associates.

427. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer pain in her right side, abnormal uterine bleeding, extreme fatigue, hair loss, and painful intercourse.

428. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

429. Additionally, after the Essure® implant, Plaintiff developed an allergy to nickel and was diagnosed with polycystic ovary syndrome.

430. On or about July 14, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at Penn State Hershey Medical Center in Hershey, Pennsylvania.

431. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Jessica Hernandez

432. Jessica Hernandez is a resident of Exton, Pennsylvania.

433. In or about February 2013, Plaintiff Jessica Hernandez underwent the Essure® procedure at Associates for Women in West Chester, Pennsylvania.

434. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

435. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, heavy and abnormal bleeding, severe abdominal pain, cramping, bloating, pain during intercourse, hormonal fluctuations, and extreme joint pain.

436. Additionally, Plaintiff experienced device migration.

437. In or about May 2016, Plaintiff underwent a hysterectomy to remove the Essure® device at Associates for Women in West Chester, Pennsylvania.

438. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control.

439. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Crystal Thornton

440. Crystal Thornton is a resident of Connellsville, Pennsylvania.

441. In or about February 23, 2012, Plaintiff Crystal Thornton underwent the Essure® procedure at Uniontown Hospital in Uniontown, Pennsylvania by Dr. Rajnikant Popat.

442. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe pelvic and abdominal pain.

443. On or about July 11, 2013, Plaintiff underwent a hysterectomy to remove the Essure® device at Uniontown Hospital in Uniontown, Pennsylvania by Dr. Rajnikant Popat.

444. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®.

445. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

446. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. Greg Thornton

447. Plaintiff Greg Thornton is a resident of Connellsville, Pennsylvania.

448. Plaintiff Greg Thornton is married to Plaintiff Crystal Thornton and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

449. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

450. Plaintiff's wife experienced severe pelvic and abdominal pain.

451. After Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

452. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

453. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

454. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

5. Shelly Howard

455. Shelly Howard is a resident of Verona, Pennsylvania.

456. On or about September 30, 2004, Plaintiff Shelly Howard underwent the Essure® procedure at UPMC Shadyside Hospital in Pittsburg, Pennsylvania by Dr. Alonzo James.

457. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer unusual bleeding, unusual periods, infections, and painful intercourse.

458. Plaintiff also experienced device migration.

459. On or about November 2014, Plaintiff underwent a hysterectomy to remove the Essure® device at the Heart of Florida Regional Medical Center in Davenport, Florida by Dr. Edmond Andha.

460. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control.

461. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she

not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

6. Sabrina Colding

462. Sabrina Colding is a resident of Philadelphia, Pennsylvania.

463. In or about September 2006, Plaintiff Sabrina Colding underwent the Essure® procedure at Delaware County Memorial Hospital in Drexel Hill, Pennsylvania.

464. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer irregular and prolonged menstruation, severe menstruation pain, abnormal menstruation, and pain during intercourse.

465. Plaintiff also experienced device migration and organ perforation.

466. On or about October 6, 2016, Plaintiff underwent a hysterectomy to remove the Essure® device at Delaware County Memorial Hospital in Drexel Hill, Pennsylvania by Dr. Elizabeth Louka.

467. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

7. Vanessa Oates

468. Vanessa Oates is a resident of Philadelphia, Pennsylvania.

469. In or about June 2015, Plaintiff Vanesa Oates underwent the Essure® procedure at Thomas Jefferson University Hospital by Dr. Sonya Lee in Philadelphia, Pennsylvania.

470. Immediately after undergoing the Essure® procedure, Plaintiff began to suffer extreme fatigue, nausea, dizziness, irregular and prolonged menstruation, severe menstruation pain, pain during intercourse, hormonal fluctuations, cramping, and bloating.

471. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

472. Plaintiff developed a cyst approximately 5.6 centimeters in diameter on her Left fallopian tube.

473. On or about April 19, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at Thomas Jefferson University Hospital by Dr. Christine Kim in Philadelphia, Pennsylvania.

474. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

8. David Oates

475. Plaintiff David Oates is a resident of Philadelphia, Pennsylvania

476. Plaintiff David Oates is married to Plaintiff Vanessa Oates and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

477. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

478. Plaintiff's wife experienced extreme fatigue, nausea, dizziness, irregular and prolonged menstruation, severe menstruation pain, pain during intercourse, hormonal fluctuations, cramping, bloating, and ovarian cysts.

479. Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores, and the couple's three children.

480. Plaintiff's wife experienced fatigue so severe that Plaintiff had to occasionally bathe, clothe, and feed his wife.

481. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

482. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

483. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

9. Maureen Burton

484. Plaintiff Maureen Burton is a resident of Norristown, Pennsylvania.

485. On or around September 16, 2013, Plaintiff Maureen Burton underwent the Essure® procedure performed by Dr. Thomas S. Dardarian at Main Line Women's Health Care in Pennsylvania.

486. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual, abdominal and back pain, rashes, as well as heavy bleeding.

487. Additionally, after being implanted with Essure® Plaintiff began experiencing painful intercourse, developed recurrent yeast infections, and endometritis.

488. Plaintiff also experienced consistently high glucose levels after the Essure implant.

489. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control and explained how the Essure® procedure was to be performed.

490. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. As a result, Plaintiff suffered from severe abdominal and back pain, as well as fatigue and depression.

491. Additionally, Plaintiff was forced to undergo the surgical removal of her right-side Essure® coil that perforated her fallopian tube.

492. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

493. Plaintiff relied to her detriment on Defendant's misrepresentations regarding the safety and effectiveness of Essure®.

Q. TENNESSEE

1. Catherine Cooper

494. Catherine Cooper is a resident of Collierville, Tennessee.

495. In or about January 2009, Plaintiff Shala Clayton underwent the Essure® procedure at the Methodist Germantown Hospital in Germantown, Tennessee.

496. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, heavy and abnormal bleeding, severe abdominal pain, cramping, bloating, hormonal fluctuations, and cysts on her ovaries.

497. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

498. In or about August of 2009, Plaintiff underwent a hysterectomy to remove the Essure®device at Methodist Germantown Hospital in Germantown, Tennessee.

499. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control.

500. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®.

501. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

502. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

R. TEXAS

1. Mikesha Barnett

503. Mikesha Barnett is a resident of Carrolton, Texas.

504. On or about October 2, 2008, Plaintiff Mikesha Barnett underwent the Essure® procedure at Obstetrics and Gynecology in Dallas, Texas by Dr. Clark Griffith.

505. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

506. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe abdominal pain and heavy bleeding.

507. On or about July 22, 2010, Plaintiff underwent a hysterectomy to remove the Essure® device at Obstetrics and Gynecology in Dallas, Texas by Dr. Clark Griffith.

508. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control.

509. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®.

510. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

511. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Titiana Brooks

512. Titiana Brooks is a resident of Fort Worth, Texas.

513. In or about September 2009, Plaintiff Tatiana Brooks underwent the Essure® procedure at Texas Health by Dr. William Maxwell.

514. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer unusual bleeding, pain and cramping, prolonged menstruation, severe abdominal pain when not menstruating, and pain during intercourse.

515. On or about May 18, 2016. Plaintiff underwent a hysterectomy to remove the Essure® device at Baylor Scott and White Hospital in Fort Worth, Texas by Dr. William Maxwell.

516. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Carmina Reyes

517. Carmina Reyes is a resident of San Antonio, Texas.

518. In or about May 2007, Plaintiff Carmina Reyes underwent the Essure® procedure at Riverwalk Obstetrics and Gynecology by Dr. Ricardo Munoz.

519. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

520. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer unusual bleeding, pain and cramping, prolonged menstruation, severe abdominal pain when not menstruating, and pain during intercourse.

521. On or about May 2013, Plaintiff underwent a partial hysterectomy to remove the Essure® device at North Central Baptist Hospital in San Antonio, Texas by Dr. Ricardo Munoz.

522. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

S. VERMONT

1. Jennifer Wise

523. Jennifer Wise is a resident of Rutland, Vermont.

524. On or about April 2005, Plaintiff Jennifer Wise underwent the Essure® procedure at Berkshire Medical Center.

525. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

526. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe abdominal pain, cramping, bloating, heavy bleeding, and prolonged menstruation.

527. Plaintiff also experienced device migration, and an unintended pregnancy.

528. On or about June 2, 2017, Plaintiff underwent a partial hysterectomy to remove the Essure® device at Rutland Regional Medical Center in Rutland, Vermont.

529. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Marc Wise

530. Plaintiff Marc Wise is a resident of Rutland, Vermont.

531. Plaintiff Marc Wise is married to Plaintiff Jennifer Wise and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

532. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

533. Plaintiff's wife experienced severe abdominal pain, cramping, bloating, heavy bleeding, prolonged menstruation, device migration, and an unintended pregnancy.

534. After Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

535. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

536. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

T. VIRGINIA

1. Deneace Walker

537. Deneace Walker is a resident of Newport News, Virginia.

538. In or about January of 2009, Plaintiff Deneace Walker underwent the Essure® procedure at Tidewater Medical Center in Chesapeake, Virginia by Dr. Laura Cordes.

539. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer abdominal pain and excessive bleeding.

540. On or about March of 2011, Plaintiff underwent a partial hysterectomy to remove the Essure® device at Riverside Hospital in Newport News, Virginia.

541. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control.

542. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®.

543. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

544. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Theresa Chandler

545. Theresa Chandler is a resident of Dumfries, Virginia.

546. On or about April 11, 2007, Plaintiff Theresa Chandler underwent the Essure® procedure by Dr. Alley K. Ramsey at Alder Obstetrics and Gynecology in Dumfries, Virginia.

547. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer serious infections resulting in prolonged hospitalization, heavy and unusual bleeding, severe abdominal pain, prolonged menstruation, hormonal fluctuations, severe bloating, and painful intercourse.

548. Plaintiff also experienced device migration, and blood clots.

549. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines – for which she had no history of suffering prior to undergoing the implantation of Essure®.

550. In or about August 2008, Plaintiff underwent removal of the Essure® device at Alder Obstetrics and Gynecology by Dr. Alley Ramsey in Dumfries, Virginia.

551. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control.

552. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a

permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Marcus Chandler

553. Plaintiff Marcus Chandler is a resident of Dumfries, Virginia.

554. Plaintiff Marcus Chandler is married to Plaintiff Theresa Chandler and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

555. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

556. Plaintiff's wife experienced serious infections resulting in prolonged hospitalization, heavy and unusual bleeding, severe abdominal pain, prolonged menstruation, hormonal fluctuations, severe bloating, painful intercourse, blood clots, and device migration.

557. After Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

558. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

559. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

560. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

U. WASHINGTON

1. Katie Frye

561. Katie Frye is a resident of Edmonds, Washington.

562. On or about December 2010, Plaintiff Katie Frye underwent the Essure® procedure at Fairfield Obstetrics and Gynecology by Dr. Andrea McCann.

563. Shortly after undergoing the Essure procedure, Plaintiff began to suffer severe abdominal pain and excessive bleeding.

564. On or about January 2011, Plaintiff underwent partial hysterectomy at Samaritan Obstetrics and Gynecology in Corvallis, Oregon by Dr. Andrea McCann.

565. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control.

566. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®.

567. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

568. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Chimene Kirkham

569. Chimene Kirkhman is a resident of Tenino, Washington.

570. In or about April 2013, Plaintiff Chimene Kirkhman underwent the Essure® procedure at South Sound Women's Center in Olympia, Washington.

571. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

572. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer unusual bleeding, pain during intercourse, bloating, and organ perforation.

573. On or about January 26, 2015, Plaintiff underwent a hysterectomy to remove the Essure® device at Providence Centralia Hospital in Centralia, Washington.

574. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device.

Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Harold Kirkham

575. Plaintiff Harold Kirkham is a resident of Tenino, Washington.

576. Plaintiff Harold Kirkham is married to Plaintiff Chimene Kirkham and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

577. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

578. Plaintiff's wife experienced unusual bleeding, pain during intercourse, bloating, and organ perforation.

579. After Plaintiff's wife was implanted with Essure®, Plaintiff became primarily responsible for tending to all household chores.

580. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

581. Plaintiff suffered lost wages as a result of transporting his wife to and from doctor's appointments on several occasions, and tending to his wife's well-being as she recovered from a hysterectomy.

582. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

583. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

XI

FRAUDULENT CONCEALMENT/DISCOVERY RULE/EQUITABLE TOLLING/EQUITABLE ESTOPPEL

A. SUMMARY OF ACTIVE CONCEALMENT

584. Defendant's fraudulent acts and/or omissions prevented Plaintiffs and/or Plaintiffs' physicians from discovering the injuries or causes thereof as alleged in this amended complaint until February 29, 2016.

585. Defendant's failure to report, document, or follow up on the known adverse event complaints, and concealment and altering of adverse events, serious increased risks, dangers, and complications, constitutes fraudulent concealment that tolls Plaintiffs' statutes of limitations.

586. Defendant is also estopped from relying on any statute of limitations defense because they continued to refute and deny reports and studies questioning the safety of Essure, actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure, and failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and Plaintiffs. As a result of Defendant's concealment of the true character, quality, history, and nature of their product, they are estopped from relying on any statute of limitations defense.

587. Defendant furthered their fraudulent concealment through acts and omissions, including misrepresenting known dangers and/or defects in Essure and/or arising out of the use

of Essure and a continued and intentional, systematic failure to disclose and/or conceal such information from/to Plaintiffs, Plaintiffs' physicians, and the FDA.

588. In short, Defendant:

a. Actively and intentionally concealed from Plaintiffs that their physicians were not trained pursuant to FDA-approved training.

b. Actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure, and failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and Plaintiffs.

c. Actively and intentionally concealed from Plaintiffs and Plaintiffs' physicians risks by making the misrepresentations/warranties discussed herein knowing they were false. In short, Defendant knew the misrepresentations were false because they had studies and reports which showed the opposite, yet altered and concealed the same from Plaintiffs, the FDA and Plaintiffs' physicians. Defendant made the misrepresentations with the intent of misleading Plaintiffs into relying on them because they had studies and reports which showed the opposite, yet decided to conceal the same (collectively "the acts and omissions").

589. If Defendant had met their duties under the applicable federal and parallel state laws, the FDA would have had the information necessary to warn the public, including Plaintiffs and Plaintiffs' physicians, of the increased risks and serious dangers associated with Essure in time to have lessened or prevented Plaintiffs' injuries, which is evidenced by the fact that the FDA is now mandating a new clinical trial, a "black box" warning, and a "patient decision checklist" which discusses and warns in detail about the risks of the very same injuries Plaintiffs suffered. Had Defendant satisfied their obligations, these FDA mandates would have been

implemented prior to Plaintiffs' implantations. However, Defendant continued to misrepresent the safety and efficacy of Essure at the FDA Hearings.

590. In short, Defendant manipulated their reports to the FDA and presented false and misleading information, which, in turn, resulted in Plaintiffs' consent to implant not being informed because critical facts regarding the nature and quality of side effects from Essure were concealed from Plaintiffs and their physicians.

591. Defendant did this in an effort to maintain the impression that Essure had a positive risk/benefit profile, to guard sales, and to ensure that Plaintiffs and their physicians did not have the salient facts in order to bring the claims alleged in this amended complaint.

592. Defendant's conduct was malicious, intentional, and outrageous, and constitutes a willful and wanton disregard for the rights and safety of Plaintiffs and others.

B. FDA CALLS ESSURE MEETING

593. The FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to hear concerns from experts and plan recommendations for Essure.

594. On February 29, 2016, the FDA first announced that it will force a major change to the Essure warning label and also require all women considering receiving Essure, to fill out a "Patient Decision Checklist" to ensure that they are fully informed of the true risks.[3]

[3] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm.

595. The FDA stated that such warnings are needed for a woman to understand the risks as compared to alternative options and then decide whether the product is right for her.[4]

596. The new warning and checklist changed the risk/benefit profile of Essure for Plaintiffs and gave rise to new salient facts which Plaintiffs and their physicians did not and could not have had prior to February 29, 2016.

597. In its current form, this patient decision checklist requires a patient's initials and signature fifteen separate times, recognizing new risks previously not disclosed.

598. Finally, women considering Essure will have the chance to be fully informed of its true risks.

599. This result is why Defendant withheld and actively concealed safety information from the FDA and the public for years.

600. Upon information and belief, Defendant knew that if the true risks of Essure were known to the FDA, they should or would inevitably be communicated to physicians and Plaintiffs.

601. The checklist specifically warns of device migration, perforation of organs, and new side effects that Defendant had been cited for hiding from the FDA, Plaintiffs, and Plaintiffs' physicians and/or enhances prior inadequate warnings.

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[4] *Id.*

602. The checklist enhances the sufficiency of the warnings given to potential Essure patients and completely alters the process of undergoing the procedure.

603. The checklist has a major impact on the risk/benefit profile of the device, and Plaintiffs would not have had the device implanted if they were aware of the true risks of Essure.

604. On February 29, 2016, the FDA also announced that it would require a detailed boxed warning for the Essure device. The FDA reserves boxed warnings, commonly referred to as "black box warnings," for only the most serious adverse events. Boxed warnings indicate the highest level of risk.

605. The FDA suggested the following warning:

> **WARNING: Some patients implanted with the Essure System for Permanent Birth Control have reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions. Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure device during discussion of the benefits and risks of the device.**[5]

606. This boxed warning directly addresses side effects that Defendant had been cited for hiding from the FDA and the public for years.

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[5] *FDA Draft Guidance on Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, issued March 4, 2016.*

C. DISCOVERY RULE – TOLLING

607. Plaintiffs did not know of the claims and their underlying facts asserted in this amended complaint, nor could any reasonable prudent person know of such claims until February 29, 2016.

608. Plaintiffs did not possess the sufficient critical facts to put them on notice that the wrongs and the acts and omissions discussed herein had been committed until such date. This is because it was not until the FDA hearing that Essure's safety and Defendant's acts and omissions were publicly called into question by the FDA and the medical community and the FDA required the "black box warning," "patient decision checklist," and "new clinical trials."

609. In fact, no reasonable person in Plaintiffs' position would have been aware of the salient facts set out in this amended complaint until after February 29, 2016.

610. Plaintiffs did not have the opportunity to discover the harm inflicted because Defendant was and continues to conceal the acts and omissions noted above.

611. At all times material hereto, Plaintiffs exercised reasonable diligence in investigating potential causes of their injuries by discussing their injuries with healthcare providers. None of the conversations gave Plaintiffs a reason to suspect, or reasonably should have given Plaintiffs a reason to suspect, that Essure or Defendant's tortious conduct was the cause of such injuries until February 29, 2016.

612. Regardless of the exercise of reasonable diligence, Plaintiffs did not know, or reasonably should not have known, that they suffered injuries and that their injuries were caused by Defendant's conduct until February 29, 2016.

613. Plaintiffs neither suspected nor knew of Defendant's wrongdoings as alleged herein until February 29, 2016.

614. In sum, Plaintiffs were reasonably unaware, and had no reasonable way of knowing, that their injuries described above were caused by Defendant's conduct until February 29, 2016.

615. As such, Plaintiffs' statute of limitations did not begin to run until February 29, 2016.

D. FRAUDULENT CONCEALMENT – EQUITABLE TOLLING

616. Defendant committed affirmative independent acts of concealment (including the acts and omissions) and intentionally mislead Plaintiffs as noted above upon which Plaintiffs and Plaintiffs' physicians relied on.

617. These acts and omissions misled Plaintiffs in regard to their causes of action and prevented them from asserting such rights because the facts which would support their causes of action as alleged in this amended complaint were not apparent to a reasonably prudent person until February 29, 2016.

618. Defendant also prevented Plaintiffs from asserting their rights by committing affirmative independent acts of concealment as noted above upon which Plaintiffs relied.

619. Due to the acts and omissions of concealment, Plaintiffs were not cognizant of the facts supporting their causes of action until February 29, 2016.

620. As such, Plaintiffs' statutes of limitations were tolled in light of Defendant's fraudulent concealment and their statutes began to run starting from the date that facts supporting their causes of action in this amended complaint became apparent, which was on or after February 29, 2016.

621. Defendant's misconduct and fraudulent concealment of the relevant facts deprived Plaintiffs and their physicians of vital information essential to the pursuit of the claims in this amended complaint, without any fault or lack of diligence on their part. Plaintiffs relied on Defendant's misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendant's tortious conduct.

E. EQUITABLE ESTOPPEL

622. In the alternative, Defendant is estopped and may not invoke the statute of limitations as a defense because, through the fraud or concealment noted above, specifically the acts and omissions, Defendant caused Plaintiffs to relax their vigilance and/or deviate from their right of inquiry into the facts as alleged in this amended complaint.

623. Defendant affirmatively induced Plaintiffs to delay bringing this amended complaint by the acts and omissions.

624. In addition to the acts and omissions noted above, Defendant consistently represented to Plaintiffs and/or Plaintiffs' physicians that Essure was not the cause of any of Plaintiffs' injuries to delay their bringing a claim against Defendant.

625. Defendant was and is under a continuing duty to monitor and disclose the true character, quality, and nature of Essure. Because of Defendant's misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendant is estopped from relying on any statute of limitations defense.

XII

FACTS AND WARRANTIES

626. Defendant failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians on how to use Essure and the necessary hysteroscopic equipment.

627. The skills needed to place the micro-inserts, as recognized by the FDA panel in the PMA process, "are way beyond the usual gynecologist".

628. Defendant went out and attempted to train the implanting physicians on how to use its device and the necessary hysteroscopic equipment. Defendant (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendant observed physicians until Defendant believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiffs that

"Physicians must be signed-off to perform Essure procedures". Defendant had no experience in training others in hysteroscopy.

629. Defendant failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians and provided hysteroscopic equipment to the implanting physicians who were not qualified to use such complicated equipment.

630. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, but not for successful placement, pain, and complication rates, evidencing that Defendant's training methods were failing[6].

631. Defendant provided hysteroscopic equipment to the implanting physicians who were not competent to use such equipment. Defendant knew the implanting physicians were not competent to use such sophisticated equipment, yet provided the equipmentregardless in order to sell its product.

632. Defendant's distribution plan of requiring the implanting physicians to purchase two (2) Essure kits a month was an unreasonably dangerous plan, as it compelled the implanting physicians to insist that Essure be used in Plaintiffs.

633. Defendant's distribution plan also included (1) negligently distributing an "adulterated" and "misbranded" device against its CPMA and federal law; (2) the promotion of Essure through representatives of the hysteroscopic equipment manufacturers, who were not

[6] *Learning curve of hysteroscopic placement of tubal sterilization micro inserts*, US National Library of Medicine, Janse, JA.

adequately trained nor had sufficient knowledge regarding Essure; (3) failing to report and actively concealing perforations which occurred as a result of Essure; (4) erroneously using non-conforming material in the manufacturing of Essure and failing to keep track of the non-conforming material; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure at an unlicensed facility and (7) manufacturing Essure for three years without a license to do so.

634. Lastly, Plaintiffs relied on several warranties which were given directly by Defendant to Plaintiffs, prior to implantation, on the internet and in the implanting physicians' offices, through Defendant's website and advertising, as outlined in detail *infra*.

XIII

COUNTS

A. NEGLIGENT TRAINING – COUNT I

635. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

636. First, Defendant undertook an independent duty to train physicians on how to properly use Essure and place the micro-inserts which failed to abide by FDA training guidelines.

637. In fact, Defendant (1) created an Essure Training Program; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendant observed physicians until Defendant believed they were competent; (4) created Essure Procedure Equipment Supplies

Checklists; and (5) represented to Plaintiffs that "Physicians must be signed-off to perform Essure procedures."

638. As part of Defendant's training, Defendant had a duty to abide by the FDA training guidelines for the implanting physicians on how to place Essure using its own delivery system, certify the implanting physicians, and oversee this particular procedure. Defendant also had a duty to disclose adverse events to the physicians so that they, in turn, could properly advise their patients of the actual risks.

639. Specifically, pursuant to the FDA approved training regulations and guidelines, Defendant had a duty to comply with the following federal requirements so that implanting physicians performed "competent procedures" and would be able to "manage possible technical issues":

(a) Ensure that the implanting physicians completed the required preceptoring (generally 5 cases) in Essure placement until competency;

(b) Ensure that the implanting physicians had read and understood the Physician Training Manual;

(c) Ensure that the implanting physicians had "successful completion of Essure Simulator Training";

640. As outlined in the Physicians Manual these requirements were necessary in order to:

(a) Ensure that the implanting physicians were selecting appropriate patients for Essure;

(b) Ensure that the implanting physicians were appropriately counseling Plaintiffs on the known risks; and

(c) Ensure the implanting physicians were qualified and competent to perform the Essure procedure to ensure proper placement to preclude migration, perforation and fracturing of coils.

641. Defendant breached this duty and parallel state laws, thereby departing from the FDA approved guidelines by:

(a) Not ensuring that the implanting physicians completed the required preceptoring in Essure placement until competency. The implanting physicians did not complete the required preceptoring until competency;

(b) Not ensuring that the implanting physicians had read and understood the Physician Training Manual. The Implanting Physicians did not understand the Physician Training Manual.

(c) Not ensuring that the implanting physicians had "successful completion of Essure Simulator Training". The implanting physicians did not successfully complete the Essure Simulator Training.

642. This departure from the training guidelines caused the Essure coils to migrate/fracture and/or perforate organs because:

(a) The Essure Training Program ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above;

(b) The required preceptoring ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above;

(c) The requirement to read and understand the Physician Training Manual ensured proper placement and without it, the Implanting Physicians'

technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above.

643. This breach caused Plaintiffs' damages as noted above.

644. As a result of Defendant's negligence individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

645. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

646. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

647. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies, along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

648. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and

suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

B. NEGLIGENCE – RISK MANAGEMENT – COUNT II

649. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

650. In short, Defendant had a duty, under both state and federal law, to have in place a reasonable risk management procedure to ensure that, *inter alia*, (1) adverse events were being reported to the FDA so that it could be relayed to the implanting physicians and/or Plaintiffs; (2) adverse reports were considered in its risk analysis and that the risk analysis was updated to reflect the same so that it could be relayed to the implanting physicians and/or Plaintiffs; (3) Defendant investigated information about the risks Essure posed so that it could be relayed to the implanting physicians and/or Plaintiffs; (4) the continued sale of Essure was appropriate and reasonable despite information being withheld from the public by Defendant; (5) Defendants monitored the product after pre-market approval to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.; (6) Defendant had internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq., and §§ 820.20 et seq.; and (7) Defendants maintained the labeling of Essure by filing a "Special PMA Supplement – Changes Being Effected" ("CBE") which allowed Defendant to unilaterally update the labeling of Essure to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d).

651. Specifically, Defendant had a duty to comply with the following federal regulations, but breached these regulations by the subsequent violations noted directly below (which Defendant were cited for by the FDA):

(a) 21 C.F.R. 814.80 – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a condition of approval specified in the PMA approval order for the device.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians. This failure to disclose and include the information in their risk management analysis was a condition of approval in its CPMA.)

(b) 21 C.F.R. 803.1(a) – This part establishes the requirements for the medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified follow up information. These reports help us to protect the public health by helping to ensure that the devices are not adulterated or misbranded and are safe and effective for their intended use.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(c) 21 C.F.R. 803.10 – (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit

reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us. (2) Submit annual reports (described in 803.33) to us. (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or (ii) Submit reports of device-related malfunctions to the manufacturer. (2) [Reserved]. (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction. (2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of: (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or (ii) A reportable event for which we made a written request. (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(d) 21 C.F.R. 803.50(a) – (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. (b) What information does FDA consider “reasonably known” to me? (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you: (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You

are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(e) 21 C.F.R. 803.53 – You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 5 work days after the day that you become aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(f) 21 C.F.R. 806.10 – (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the act caused by the device, which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is

exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. (c) The manufacturer or importer shall include the following information in the report: (1) The seven-digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven-digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven-digit registration number will be assigned a seven-digit central file number by the district office reviewing the reports. (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal. (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device. (4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA. (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report. (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken. (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers. (9) The total number of

devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal. (10) The date of manufacture or distribution and the device's expiration date or expected life. (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee. (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted. (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available. (e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury. (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter. [62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013].

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose

coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(g) 21 C.F.R. 814.84 – (a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device. (b) Unless FDA specifies otherwise, any periodic report shall: (1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b). (2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA: (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(h) 21 C.F.R. 820.65 – Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

(Defendant breached this federal standard by failing to establish and maintain procedures for identification of each Essure unit which in turn precluded proper corrective actions and led to the failure to disclose and include in their risk management analysis thousands of adverse events and complaints for migrations, perforations, pregnancies, and device failures and malfunctions, which in turn were never disclosed to Plaintiffs and Implanting Physicians. This failure to disclose and include in their risk management analysis was a condition of approval in its CPMA).

(i) 21 C.F.R. 822 – Post market surveillance. This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (FDCA) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria: (a) Failure of the device would be reasonably likely to have serious adverse health consequences; (b) The device is intended to be implanted in the human body for more than one (1) year;…The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. This data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

(Defendant was cited for and breached this federal standard by failing to comply with postmarket surveillance plans. Specifically, by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians. Defendant further breached this federal standard by not withdrawing its product from the market.)

(j) 21 C.F.R. 820.180 – All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those note stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands

of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(k) 21 C.F.R. 820.198 – (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the

manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(l) FDA requirement in CPMA order – "Within 10 days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(m) FDA requirement in CPMA order – "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(n) Monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq..

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations,

pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physician.)

(o) Establish internal procedures for reviewing complaints and event reports, 21 CFR §§820.198, §§ 820.100 et seq. and §§ 820.20 et seq.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

652. Due to these breaches, Defendant was cited by the FDA as Defendant "did not consider these complaints in their risk analysis" and "for their risk analysis of Essure being incomplete".

653. This was an unreasonably dangerous and negligent risk analysis plan which was required by federal law as it put Plaintiffs at unnecessary risk of injury due to Defendant's failure to report adverse reports to the FDA, to track non-conforming product, update its labeling of Essure, and to consider adverse reports in its risk analysis.

654. This breach caused Plaintiffs' damages because but for Defendant's failure to comply with federal law and disclose, consider, and include in their risk management plans and/or labeling the thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, Plaintiffs would not have been implanted with Essure and therefore would also not have been injured by Essure. Instead, Defendant failed to have a complete Risk Management Plan in place, thereby precluding Plaintiffs and their implanting physicians from knowing of the thousands of migrations, perforations, pregnancies, device failures and malfunctions. This was actively concealed by Defendant.

655. This breach caused Plaintiffs' injuries and damages noted above.

656. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

657. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment, and rehabilitation into the indefinite future.

658. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

659. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies, along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

660. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

C. BREACH OF EXPRESS WARRANTY – COUNT III

661. Plaintiffs re-allege and re-incorporate the preceding paragraphs and plead in the alternative to Counts IV.

662. The FDA's CPMA order confirms that: the FDA "does not evaluate information related to contractual liability warranties, however, you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

663. This claim arises out of injuries caused by Defendant's express warranties to Plaintiffs which were specifically negotiated and expressly communicated to Plaintiffs by Defendant or its agents in such a manner that Plaintiffs understood and accepted them.

664. Defendant made, and Plaintiffs relied on, the following actual affirmations of fact or promises which formed the bases of the bargain between Plaintiffs and Defendant[7]:

a. "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty which was located on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

[7] The warranties and misrepresentations relating to pregnancy apply to only those plaintiffs that became pregnant.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

b. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiffs. "There were Zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiffs.

c. "Physicians must be signed-off to perform Essure procedures"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted reliable physicians who were approved to perform their surgery.

iii. However, this warranty was false as Defendant failed to abide by FDA guidelines when training the implanting physicians and "signed-off" on the implanting physicians who did not have the

requisite training. Defendant concealed this information from Plaintiff.

iv. "Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"

v. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

vi. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

vii. However, this warranty was false as several pregnancies have been reported subsequent to confirmation. Defendant concealed this information from Plaintiffs. Between 1997-2005, 64 pregnancies were reported to Defendant. Defendant concealed this information from Plaintiffs. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three-month Confirmation Test was performed. Defendant concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." Women who have Essure have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater.[8] Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

[8] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

d. "Essure is the most effective permanent birth control available – even more effective than tying your tubes or a vasectomy."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendant's SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendant. Defendant stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendant concealed this information from Plaintiffs. In fact, women who have Essure have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[9].

e. "Correct placement…is performed easily because of the design of the micro-insert"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly

[9] *Id.*

positioned.

iii. However, this warranty was false as Defendant admitted that placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendant concealed this information from Plaintiffs.

f. "Essure is a surgery-free permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure is not permanent because the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

g. "Zero pregnancies" in its clinical or pivotal trials.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "Are you Ready?" The circumstances under which Plaintiffs encountered this representation was via a brochure given to her at her implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendant concealed this information from Plaintiffs.

iv. In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

v. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an Essure advertisement. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

vi. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted reliable physicians who were approved to perform their surgery.

vii. However, this warranty was false as Defendant "signed off" on Essure physicians who did not perform the procedure every 6-8 weeks, including the implanting physicians. Defendant concealed this information from Plaintiffs.

h. You'll never have to worry about unplanned pregnancy again.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled, "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when

they were researching options of birth control or online.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendant concealed this information from Plaintiffs.

i. Defendant marketed with commercials stating during the procedure: "the tip of each insert remains visible to your doctor, so proper placement can be confirmed."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Essure does not allow for visual confirmation of proper placement during the procedure.

j. "Worry free"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that they did not have to worry about working or causing serious health problems.

iii. However, Defendant actively concealed and failed to report eight (8) perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued by the FDA to Defendant. Defendant actively concealed this from Plaintiffs. Defendants were issued another Form 483 when it "erroneously used non-conforming material". Defendans actively concealed this and were issued an additional Form 483 for "failing to adequately document the situation." Defendant actively concealed this from Plaintiffs. Defendant's facility was also issued a notice of violation as it "no longer uses pre-sterile and post-sterile cages". Defendant actively concealed this from Plaintiffs. Defendant also was issued a notice of violation when they "failed to obtain a valid license…prior to manufacturing medical devices". Defendant was manufacturing devices for three years without a license. Defendant actively concealed this from Plaintiffs. Defendant was also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. Defendant actively concealed this from Plaintiffs. Defendant failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%". Defendant was issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

k. "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled, "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that implanting physicians could confirm they were placed properly and would not migrate or cause other health problems.

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendant actively concealed this information from Plaintiffs. Defendant actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued to Defendant by the FDA. Defendant was issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

l. "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled, "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendant actively concealed this from Plaintiffs. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendant also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most egregiously, Defendant was issued another Form 483 when it "erroneously used non-conforming material." Defendant actively concealed this and were issued another Form 483 for "failing to adequately document the situation."

m. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendant also stated that it is only after "The Confirmation" test that pregnancy cannot occur, i.e., the complete opposite of what is warranted in the brochure.

Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was performed. Between 1997-2005, 64 pregnancies were reported to Defendant. Defendant concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked". There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test.[10]

n. "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure is not "surgery-free"; rather, surgery is not required. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%".

[10] *Essure insert expulsion after 3-month hysterosalpingogram,* US National Library of Medicine, Garcia, Al.

o. Essure is a …permanent birth control procedure-without … the risks of getting your tubes tied.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiffs.

p. "The inserts are made from…safe, trusted material."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, Defendant refers to Essure and classify it as a "drug."

q. Defendant's Essure booklet warrants: "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty in a booklet advertisement entitled "Essure: Permanent Birth Control". The circumstances under which Plaintiffs encountered this representation was via a brochure given to them at their implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause other health problems. Moreover, Plaintiffs wanted a birth control that did not irritate their uterus like other forms of birth control.

iii. However, this warranty was false because Essure does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendant concealed this information from Plaintiffs. Defendant actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483. Defendant was issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

r. "there was no cutting, no pain, no scars…"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that did not cause pain, cutting or scars like other forms of birth control do.

iii. However, this warranty was false as Plaintiffs have experienced pain as a result of Essure. Defendant concealed this information from Plaintiffs. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendant was issued Form 483s for not disclosing MDRs to the FDA for pain. Defendant altered the records of at least one trial participant to reflect less pain.

665. Defendant's "affirmations of fact or promise" and "descriptions" created a basis of the bargain for Plaintiffs as noted above.

666. The warranties were specifically negotiated, directed, intended, and expressly communicated to Plaintiffs in such a manner that Plaintiffs understood and accepted them. Moreover, Plaintiffs provided reasonable notification of the breach.

667. These warranties, in effect, over-promoted Essure and nullified otherwise adequate warnings.

668. As a result of Defendant's warranties and Plaintiffs' reliance on same, Plaintiffs have suffered damages. Specifically, the Essure device did not perform as warranted and instead migrated, perforated, broke, and/or caused other injuries noted above.

669. As a result of Defendant's breaches individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

670. As a result of Defendant's breaches, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

671. As a result of Defendant's breaches, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

672. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

673. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

D. NEGLIGENT MISREPRESENTATION – COUNT IV

674. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

675. Defendant made the following misrepresentations:

a. "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty which was located on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiffs.

b. "There were Zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiffs.

c. "Physicians must be signed-off to perform Essure procedures"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable physician who was approved to perform the surgery.

iii. However, this warranty was false as Defendant failed to abide by the FDA guidelines when training the implanting physicians and "signed-off" on the implanting physicians who did not have the requisite training. Defendant concealed this information from Plaintiffs.

d. "Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as several pregnancies have been reported subsequent to confirmation. Defendant concealed this information from Plaintiffs. Between 1997-2005, 64 pregnancies were reported to Defendant. Defendant concealed this information from Plaintiffs. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three-month Confirmation Test was performed. Defendant concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked". Women who have Essure have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater.[11] Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%".

e. "Essure is the most effective permanent birth control available – even more effective than tying your tubes or a vasectomy."

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[11] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization*, Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendant's SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendant. Defendant stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendant concealed this information from Plaintiffs. In fact, women who have Essure have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[12].

f. "Correct placement…is performed easily because of the design of the micro-insert."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

[12] *Id.*

iii. However, this warranty was false as Defendant admitted that placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendant concealed this information from Plaintiffs.

g. "The Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted an implanting physician that was properly trained on placing the device and managing any technical issues.

iii. However, this warranty was false as Defendant failed to train the implanting physicians pursuant to the FDA guidelines. Defendant concealed this information from Plaintiffs.

h. "Essure is a surgery-free permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendant's website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the

internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure is not permanent as the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

i. "Zero pregnancies" in its clinical or pivotal trials.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "Are you Ready?" The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendant concealed this information from Plaintiffs.

j. In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an Essure advertisement. The circumstances under which Plaintiffs encountered this representation was via a brochure at the implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable physician who was approved to perform surgery.

iii. However, this warranty was false as Defendant "signed off" on "Essure physicians" who did not perform the procedure every 6-8 weeks, including the implanting physicians. Defendant concealed this information from Plaintiffs.

k. You'll never have to worry about unplanned pregnancy again.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendant concealed this information from Plaintiffs.

l. Defendant marketed with commercials stating during the procedure: "The tip of each insert remains visible to your doctor, so proper placement can be confirmed."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Essure does not allow for visual confirmation of proper placement during the procedure.

m. "Worry free"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that they did not have to worry about working or causing serious health problems.

iii. However, Defendant actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued by the FDA to Defendant. Defendant actively concealed this from Plaintiffs. Defendant were issued another Form 483 when it "erroneously used non-conforming material." Defendant actively concealed this and were issued an additional Form 483 for "failing to adequately document the situation." Defendant actively concealed this from Plaintiffs. Defendant's facility was also issued a notice of violation as it "no longer uses pre-sterile and post-sterile cages." Defendant actively concealed this from Plaintiffs. Defendant also were issued a notice of violation when they "failed to obtain a valid license…prior to manufacturing medical devices." Defendant was manufacturing

devices for three years without a license. Defendant actively concealed this from Plaintiffs. Defendant was also issued a notice of violation as they were manufacturing medical devices at an unlicensed facility. Defendant actively concealed this from Plaintiffs. Defendant failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendant were issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

n. "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause other health problems.

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendant actively concealed this information from Plaintiffs.

Defendant actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483 issued to Defendant by the FDA. Defendants were issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

o. "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendantsactively concealed this from Plaintiffs. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendant also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most

egregiously, Defendant was issued another Form 483 when they "erroneously used non-conforming material." Defendant actively concealed this and were issued another Form 483 for "failing to adequately document the situation".

p. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendant also state that it is only after "The Confirmation" that pregnancy cannot occur, i.e., the complete opposite of what is warranted in the brochure. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed. Between 1997-2005, 64 pregnancies were reported to Defendant. Defendant concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[13].

q. "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures."

[13] *Essure insert expulsion after 3-month hysterosalpingogram,*, US National Library of Medicine, Garcia, Al.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure is not "surgery-free", rather surgery is not required. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%".

r. "Essure is a …permanent birth control procedure – without … the risks of getting your tubes tied."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiffs.

s. "The inserts are made from…safe, trusted material."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, cause injuries, and contain drugs. In fact, Defendant refers to Essure and classify it as a "drug."

t. Defendant's Essure booklet warrants: "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty in a booklet advertisement entitled "Essure: Permanent Birth Control." The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause other health problems. Moreover, Plaintiffs wanted a birth control that did not irritate their uterus like other forms of birth control.

iii. However, this warranty was false as Essure does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendant concealed this information from Plaintiffs. Defendant actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483. Defendant was issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

u. "there was no cutting, no pain, no scars…"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty in a booklet advertisement entitled "Essure: Permanent Birth Control." The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that did not cause pain, cutting or scars like other forms of birth control do.

iii. However, this warranty was false as Plaintiffs experienced pain as a result of Essure. Defendant concealed this information from Plaintiffs. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendant was issued Form 483s for not disclosing MDRs to the FDA for pain. Defendant altered the records of at least one trial participant to reflect less pain.

676. Plaintiffs justifiably relied on the misrepresentations. Specifically, Plaintiffs would have never had Essure implanted had they been aware of the falsity of the representations specifically delineated in the preceding paragraphs which violate both federal law and the CPMA.

677. Moreover, these misrepresentations, in effect, over-promoted Essure and nullified otherwise adequate warnings.

678. As a result of Defendant's misrepresentations and Plaintiffs' reliance on same, Plaintiffs have suffered damages. Specifically, the Essure device did not perform as represented and instead migrated, perforated, broke and/or caused other injuries, all to Plaintiffs' damage.

679. As a result of Defendant's negligence individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

680. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

681. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

682. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies, along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

683. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

E. NEGLIGENCE – FAILURE TO WARN – COUNT V

684. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

685. Plaintiffs' injuries were caused by the negligent and reckless conduct of Defendant in failing to warn Plaintiffs or their implanting physicians, all of which hinge on violations of federal law and its CPMA.

686. Defendant had a duty to warn Plaintiffs and/or their implanting physicians consistent with federal law and its CMPA which included:

(a) 21 C.F.R. 814, governing premarket approval of medical devices, a *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

(b) 21 C.F.R. 814.80 – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a condition of approval specified in the PMA approval order for the device.

(c) 21 C.F.R. 820.65 – establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.

(d) 21 C.F.R. 803.1(a) – This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified follow up. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(e) 21 C.F.R. 803.10 – (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you

become aware of a reportable event: (i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us. (2) Submit annual reports (described in 803.33) to us. (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or (ii) Submit reports of device-related malfunctions to the manufacturer. (2) [Reserved]. (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction. (2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of: (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or (ii) A reportable event for which we made a written request. (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

(f) 21 C.F.R. 803.50(a) – (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. (b) What information does FDA consider "reasonably known" to me? (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you: (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain

any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(g) 21 C.F.R. 803.53 – You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 5 work days after the day that you become aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(h) 21 C.F.R. 806.10 – (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. (c) The manufacturer or importer shall include the following information in the report: (1) The seven-digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation “C” or “R”. For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven-digit registration number may use

seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven-digit registration number will be assigned a seven digit central file number by the district office reviewing the reports. (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal. (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device. (4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA. (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report. (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken. (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers. (9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal. (10) The date of manufacture or distribution and the device's expiration date or expected life. (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee. (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted. (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the

information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available. (e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury. (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter. [62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013].

(i) 21 C.F.R. 814.84 – (a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device. (b) Unless FDA specifies otherwise, any periodic report shall: (1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b). (2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA: (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

(j) 21 C.F.R. 820.65 – Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

(k) 21 C.F.R. 822 – Post market surveillance – This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (FDCA) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria: (a) Failure of the device would be reasonably likely to have serious adverse health consequences; (b) The device is intended to be implanted in the human body for more than 1 year;… The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

(l) 21 C.F.R. 820.100(a) 6-7 – Corrective and Preventive Action – (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems; (2) Investigating the cause of nonconformities relating to product, processes, and the quality system; (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such

product or the prevention of such problems; and (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. (b) All activities required under this section, and their results, shall be documented.

(m) 21 C.F.R. 820.70(e)(h) (a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include: (1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production; (2) Monitoring and control of process parameters and component and device characteristics during production; (3) Compliance with specified reference standards or codes; (4) The approval of processes and process equipment; and (5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples. (b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40. (e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality. (h) *Manufacturing material.* Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

(n) 21 C.F.R. 820.90 – (a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a

determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented. (b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use. (2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

(o) 21 C.F.R. 820.90 – (a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate. (b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

(p) 21 C.F.R. 820.180 – All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(q) 21 C.F.R. 820.198 – (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such

procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

(r) 21 C.F.R. 820.30 – Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(s) 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a) – A drug or device shall be deemed to be misbranded…if its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.

(t) 21 U.S.C. 351(a) (h) – A drug or device shall deemed to be adulterated…if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if it is…not in conformity with…an applicable condition prescribed by an order.

(u) 21 U.S.C. 352 (q) (r) – Restricted devices using false or misleading advertising or used in violation of regulations. In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in

regulations which shall be issued by the Secretary after an opportunity for a hearing.

(v) FDA requirement in CPMA order – "Within 10 days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

(w) FDA requirement in CPMA order – "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(x) FDA requirement in CPMA order – Report Due Dates – six month, one year, eighteenth month, and two year reports.

(y) FDA requirement in CPMA order – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

(z) FDA requirement in CPMA order – Warranties are truthful, accurate, and not misleading…Warranties are consistent with applicable federal and state law.

687. Defendant breached these duties by not complying with the CPMA or federal law:

(a) Defendant failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteenth month and two year reports. All reports failed to meet the respective deadlines.

(b) Defendant failed to document successful placement of Essure concealing the failure rates.

(c) Defendant failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report 8 perforations which occurred as a result of Essure and was cited for the same by the FDA via Form 483.

(d) Defendant failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury concealing the injuries. Again, Defendant failed to report 8 perforations as adverse events which occurred as a result of Essure to the FDA as evidenced in Form 483.

(e) Defendant failed to notice the FDA of their internal excel file containing 16,047 entries of complaints.

(f) Defendant excluded the risk assessment for safety of loose coils in its Risk Management Plan and stated that Defendant had violated the FDCA.

(g) Erroneously using non-conforming material in the manufacturing of Essure.

(h) Failing to use pre-sterile and post-sterile cages.

(i) Manufacturing Essure at an unlicensed facility.

(j) Manufacturing Essure for three years without a license to do so.

(k) Not reporting … complaints in which their product migrated.

(l) Not considering these complaints in their risk analysis for the design of Essure.

(m) Failing to document CAPA activities for a supplier corrective action.

(n) On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." Form 483/Violation form issued by Timothy Grome on January 6, 2011. These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes. Defendant were issued these violations for dates of incidents 5/11/10, 9/1/10, 10/1/10, 10/5/10, 10/26/10, 11/3/10, 11/5/10, and 11/16/10.

(o) Defendant had notice of 168 perforations but only disclosed 22 to the FDA.

(p) On January 6, 2011, Defendant were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure did not include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

(q) On January 6, 2011, Defendant was cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendant's Design. The FDA also found that Defendant's CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendant's engineers learned of this and it was not documented.

(r) On July 7, 2003, Defendant was cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

(s) On July 7, 2003, Defendant was cited for not following procedures used to control products which did not confirm to specifications.

(t) Defendant failed to disclose to Plaintiffs and their implanting physicians the fact that Defendant altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.

688. Had Defendant disclosed such information as was required by the CPMA and federal law to Plaintiffs or the Implanting Physicians, Plaintiffs would never have had Essure implanted and would have avoided their injuries.

689. At all times referenced herein, Defendant and each of them were acting as agents and employees of each of the other Defendant and were acting within the scope, purpose and authority of that agency and employment and with full knowledge, permission and consent of each other Defendant.

690. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs sustained the injuries noted above.

691. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

692. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

693. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies, along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

694. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

XIV

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount according to proof at the time of trial;

2. Past and future economic and special damages according to proof at trial;

3. Loss of earnings and impaired earning capacity according to proof at trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. Equitable relief as the Court deems just and proper;

6. Declaratory judgment that Defendant is liable to Plaintiffs for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendant's wrongdoing;

7. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;

8. Punitive or exemplary damages according to proof at the time of trial;

9. Costs of suit incurred herein;

10. Pre-judgment interest as provided by law; and

11. Such other and further relief as the Court may deem just and proper.

Dated: September 5, 2017 By: */s/ C. Moze Cowper*

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JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: September 5, 2017 By: */s/ C. Moze Cowper*

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